

ANTI-IgE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 63/512,051, filed July 5, 2023, the content of which is hereby incorporated by reference in its entirety.

REFERENCE TO AN ELECTRONIC SEQUENCE LISTING

[0002] The content of the electronic sequence listing (146392066840seqlist.xml; Size: 10,949 bytes; and Date of Creation: July 19, 2023) is herein incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0003] The present disclosure provides methods and kits for treating or preventing an allergic reaction to a food allergen consumed by a human subject with one or more food allergies. In particular, the present disclosure provides prophylactic therapies comprising administration of an anti-IgE antibody at a specific dose to a human subject who is allergic to one or more food allergens.

BACKGROUND OF THE INVENTION

[0004] Food allergy affects approximately 15 million patients in the U.S., including six million children. It causes substantial morbidity and mortality, and it is the most common cause of anaphylaxis in pediatric patients seen in emergency departments across the U.S. (Gupta et al., JAMA Pediatr, 167:1026-1031, 2013). Significant consequences, including death, can result from exposure to food allergens by patients who are allergic to those food allergens, and the standard of care is merely avoidance of those food allergens. Often, life-saving treatment with antihistamines and epinephrine autoinjectors is necessary for acute allergic reactions to food allergens.

[0005] While an oral immunotherapy for peanut allergy has been approved by the United States Food and Drug Administration (USFDA), substantial gaps remain. Most important among these gaps include treatment for foods other than peanut and treatment of patients who are allergic to multiple foods. This is an unmet need, as 40% to 70% of children and adults with peanut allergy are indeed allergic to other foods (Sicherer et al., J Allergy Clin Immunol, 133:291-307, 2014; and Brough et al., J Allergy Clin Immunol, 145:1231-

1239, 2020). There is, therefore, a substantial need for improved therapies for reducing or preventing allergic reactions to food allergens in patients allergic to those food allergens.

SUMMARY OF THE INVENTION

[0006] The present disclosure provides methods and kits for treating a subject having or diagnosed with a food allergy to one or more food allergens. In particular, the present disclosure provides prophylactic therapies comprising administration of an anti-IgE antibody at a specific dose and frequency to a human subject who is allergic to one or more food allergens.

BRIEF DESCRIPTION OF DRAWINGS

[0007] **FIG. 1** is a flow chart of a study design for testing omalizumab in food allergy, including Screening, Stage 1, and Stage 1 open label extension phases of the study as described in Example 1 herein.

[0008] **FIG. 2** is a dosing table for omalizumab based on body weight and baseline total serum IgE of the patient. The dosing frequency is indicated by each cell: gray shading is once every 4 weeks; no shading is once every 2 weeks; and black shading is do not dose.

DETAILED DESCRIPTION OF THE INVENTION

[0009] The present disclosure provides methods and kits for treating a human subject having or diagnosed with a food allergy to one or more food allergens. In some embodiments, the subject is practicing food avoidance. In other embodiments, the subject has or may accidentally consume a food containing the one or more food allergens. In some embodiments, the subject is at risk of being exposed to the one or more food allergens. In some embodiments, the treating prevents or reduces an allergic reaction in the subject following consumption of food containing the one or more food allergens. In particular, the present disclosure provides prophylactic therapies comprising administration of an anti-IgE antibody at a specific dose and frequency to a human subject. In some embodiments, the human subject is allergic to one or more food allergens. In some embodiments, the human subject is allergic to peanuts and one, two or more additional food allergens. In some embodiments, the subject is a child. In some embodiments, the child is less than 6 years of age. In some embodiments, the child is from 1 to 5 years of age. In a preferred embodiment, the anti-IgE antibody is omalizumab.

[0010] As described in Example 1, a Phase 3 clinical study (OUtMATCH) is being conducted to study the use of omalizumab for the treatment of patients with a food allergy. In Stage 1 of the study, omalizumab monotherapy was found to be surprisingly safe and effective. Specifically, this outcome was particularly striking in young children (1-5 years of age), for whom XOLAIR® (omalizumab marketed by Genentech USA, Inc., South San Francisco, CA, and Novartis Pharmaceuticals Corporation, East Hanover, NJ) has not been previously approved by the USFDA for other indications (persistent allergic asthma, nasal polyps, and chronic spontaneous urticaria). This finding is a major advance in the treatment of children with multiple food allergies and is an effective therapy without the need for a food-specific treatment such as oral immunotherapy (OIT).

[0011] Successful completion of this study depended in part on design of a new dosing table which accommodates patients having a body weight ranging from 10-20 kg and having baseline total serum IgE levels as high as 1850 IU/mL. Omalizumab doses for these weights and serum IgE levels had not been previously determined because there have been no prior regulatory approvals of omalizumab for patients under 6 years of age. Moreover, patients suffering from food allergies on average have higher baseline total serum IgE levels. For example, the average baseline total serum IgE levels for subjects enrolled in a phase 3 study for use of omalizumab to treat asthma was 172.5 IU/ml (Busse et al., J Allergy Clin Immunol, 108:184-190, 2001), while the average baseline total serum IgE levels for subjects enrolled in two phase 3 studies for use of omalizumab to treat nasal polyps was 168 IU/mL and 218 UI/mL, respectively (Xolair® Prescribing Information). The subjects enrolled in this OUtMATCH study had an average baseline total serum IgE level of 810 IU/mL. Accordingly, it was important to determine doses which were high enough to produce a therapeutic benefit by reducing levels of serum IgE from relatively high baseline levels while also ensuring an acceptable safety profile.

Definitions

[0012] As used herein and in the appended claims, the singular forms “a,” “an,” and “the” include plural references unless indicated otherwise. For example, “a food allergy” includes one or more food allergies.

[0013] The phrase “comprising” as used herein is open-ended, indicating that such embodiments may include additional elements. In contrast, the phrase “consisting of” is closed, indicating that such embodiments do not include additional elements (except for trace

impurities). The phrase “consisting essentially of” is partially closed, indicating that such embodiments may further comprise elements that do not materially change the basic characteristics of such embodiments.

[0014] The term “about” as used herein in reference to a value, encompasses from 95% to 105% of that value. For instance, a dose of about 150 g/L omalizumab refers to a dose of from 142.5 g/L omalizumab to 157.5 g/L omalizumab and includes 150 g/L omalizumab.

[0015] A “food allergen” is a food, typically a food containing protein(s), that can trigger an allergic reaction upon consumption of the food or at times just exposure to minute amounts of the food by a sensitive individual. Common food allergens of human subjects are peanut, milk, egg, cereal (e.g., wheat, barley, oats, etc.), tree nuts (cashew, hazelnut, walnut, etc.), sesame, soy, crustaceans (e.g., crab, oyster, shrimp, etc.) and fish (e.g., bass, flounder, cod, etc.).

[0016] The term “total serum IgE” or “serum total IgE” refers to a total amount of IgE present in a serum sample. Serum total IgE can be measured, for example, by an ELISA (enzyme-linked immunosorbent assay). One example of an ELISA to measure serum total IgE is the ImmunoCAP® assay (ThermoFisher Scientific). “Total IgE” includes free, unbound IgE and IgE complexed with a binding partner. “Free IgE” refers to IgE not bound to a binding partner.

[0017] The term “allergen-specific IgE” as used herein refers to IgE that is specific to a particular antigen, resulting from an initial exposure to allergen in a process known as allergy sensitization. In this process, the IgE binds the surface of mast cells and basophils resulting in the activation of mast cells and basophils upon subsequent exposure to the same allergen.

[0018] As used herein, a “baseline” level, such as baseline level for body weight, serum total IgE, and allergen-specific IgE, in a human refers to the body weight of the subject or the level (concentration) of serum total IgE before the first dose of an anti-IgE antibody. These may be referred to herein as “pretreatment” values.

[0019] As used herein, the term “treatment” can include “prevention” or “reduction.” As used herein, the term “prevention” includes providing prophylaxis with respect to occurrence or recurrence of an IgE-mediated disorder (e.g., allergic reaction to a food allergen) in an individual (e.g., human subject). As used herein, the term “reduction” includes lessening of the severity of symptoms as described in Table 1-1.

[0020] An “effective amount” or “therapeutically effective amount” of an agent or, e.g., a pharmaceutical formulation comprising the agent, refers to an amount effective, at dosages and for periods of time or at dosing frequency necessary, to achieve the desired therapeutic or prophylactic result, such as a measurable improvement in the state, e.g., reduction in symptoms such as those commonly experienced by a subject suffering from a food allergy. A therapeutically effective amount may reduce or prevent symptoms of a disorder.

[0021] As used herein, the terms, “prophylaxis,” “prophylactic,” “prophylactically,” and the like refer to treatment to protect a subject from the occurrence or recurrence of an IgE-mediated disorder (e.g., allergic reaction to a food allergen) resulting from intentional or accidental exposure to or consumption of a food allergen.

[0022] The terms “determine” and “determining” as used herein refer to ascertaining a particular fact or piece of information about a patient, e.g., using an ELISA to determine the serum total IgE of a subject. Determining includes, e.g., querying a subject or referring to a document which contains the fact or piece of information about a subject, such as the body weight and/or serum total IgE of a patient.

[0023] The terms “allergic reaction” and “allergic response” as used herein refer to the experience by a human subject who is exposed to and/or consumes a food containing a food allergen to which the human subject is allergic, wherein the human subject experiences or exhibits dose-limiting symptoms which are mild, moderate, and/or severe symptoms which are characteristic of an allergic reaction to a food allergy.

[0024] The term “dose-limiting symptoms” or “food allergy reaction symptoms” as used herein refers to symptoms experienced by a subject having a food allergy wherein when the subject experiences a food allergic response or allergic reaction to one or more food allergens, the subject experiences one or more dose-limiting symptoms involving the skin, respiratory tract, and/or gastrointestinal tract, as well as neurological and/or circulatory symptoms.

[0025] The terms “mild,” “moderate,” and “severe” as used herein to characterize an allergic reaction in a subject which may be assessed by a trained expert (e.g., clinician or medical doctor) on food allergies and exposure to a food allergen. The grading scale used to define dose-limiting symptoms is shown below in Table 1-1.

Table 1-1. Dose-Limiting Symptoms

Severity	Symptoms
Mild	<p>Skin: limited or localized hives, swelling (e.g., mild lip edema), skin flushing (e.g., few areas of faint erythema) or mild pruritus (e.g., occasional scratching).</p> <p>Respiratory: rhinorrhea (e.g., occasional sniffing or sneezing), nasal congestion, occasional cough, throat discomfort.</p> <p>GI: mild abdominal discomfort (including mild nausea with or without decreased activity), isolated emesis thought to be secondary to gag.</p>
Moderate	<p>Skin: systemic hives (e.g., numerous or widespread hives), swelling (e.g., significant lip or face edema), pruritus causing protracted scratching, more than a few areas of erythema or pronounced erythema.</p> <p>Respiratory: throat tightness without hoarseness, persistent cough, wheezing without dyspnea.</p> <p>GI: persistent moderate abdominal pain/cramping/nausea with decreased activity, vomiting.</p>
Severe	<p>Skin: severe generalized urticaria/angioedema/erythema.</p> <p>Respiratory: laryngeal edema, throat tightness with hoarseness, wheezing with dyspnea, stridor.</p> <p>GI: severe abdominal pain/cramping/repetitive vomiting.</p> <p>Neurological: change in mental status.</p> <p>Circulatory: clinically significant hypotension</p>

[0026] The term “oral immunotherapy” or “OIT” as used herein, refers to feeding a food allergen to an allergic individual in an increasing amount in order to desensitize the individual to the food. For instance, oral immunotherapy to peanut involves feeding peanut to an allergic individual at increasing amounts over a period of time to increase the threshold of peanut (amount in milligrams) that would trigger an allergic reaction upon consumption by the individual.

[0027] As used herein, the term “food avoidance” refers to the active effort or intent by a subject to not ingest or consume any foods that do or may contain a food allergen to which the subject knows or suspects he is allergic. A subject who practices food avoidance may accidentally be exposed to or unintentionally ingest or consume a food that contains the allergen(s) to which that subject is allergic.

I. Anti-IgE Antibodies

[0028] The methods, uses, medicaments and kits of the present disclosure for treating or preventing an allergic reaction to a food allergen consumed by a human subject with a food allergy to one or more food allergens involve administration of an anti-IgE antibody at a specific dose and frequency to the subject. In some embodiments, the subject is allergic to peanuts. In some embodiments, the subject is allergic to peanuts and one, two, or more additional food allergens. The anti-IgE antibodies of the methods and kits of the present disclosure block binding of human IgE to the high affinity human IgE Receptor (Fc ϵ RI). In some embodiments, the anti-IgE antibody is omalizumab or monoclonal antibody comprising CDR-H1 (GYSITSGY, set forth as SEQ ID NO:5), CDR-H2 (TYDGS, set forth as SEQ ID NO:6), CDR-H3 (GSHYFGHWFAV, set forth as SEQ ID NO:7), CDR-L1 (RASQSVDDYDGDSYMN, set forth as SEQ ID NO:8), CDR-L2 (AASYLES, set forth as SEQ ID NO:9) and CDR-L3 (QQSHEDPYT, set forth as SEQ ID NO:10). In some preferred embodiments, the anti-IgE antibody is omalizumab. In other preferred embodiments, the anti-IgE antibody is a biosimilar of omalizumab.

[0029] Omalizumab (CAS Registry No. 242138-07-4) is a recombinant DNA-derived, humanized IgG1 monoclonal antibody with a molecular weight of approximately 149 kDa that selectively binds to human IgE. The amino acid sequences of the heavy chain variable region (VH) and the light chain variable region (VL) of omalizumab are shown as the E25 sequences in Figure 2 of U.S. Patent No. 6,172,213, and are set forth herein as SEQ ID NO:1 and SEQ ID NO:2, respectively. The amino acid sequences of the full length heavy chain and the full length light chain of omalizumab are shown as the E25 sequences in Figure 12 of U.S. Patent No. 6,172,213, and are set forth herein as SEQ ID NO:3 and SEQ ID NO:4, respectively.

[0030] Omalizumab is designed to treat IgE-mediated disease by reducing the concentration of free IgE in blood and in tissue. Omalizumab selectively binds to human IgE at the same site of the IgE molecule that binds to the high affinity IgE Receptor (Fc ϵ RI), thereby reducing IgE bound to the surface of basophils, mast cells, and dendritic cells and reducing basophil, mast cell, and dendritic cell-triggered Type 2 inflammation.

[0031] XOLAIR® (omalizumab marketed by Genentech USA, Inc., South San Francisco, CA, and Novartis Pharmaceuticals Corporation, East Hanover, NJ) is approved by the European Commission and the USFDA for treatment of other indications in older

children and adults. Specifically, omalizumab is approved for patients with moderate-to-severe persistent asthma who are 6 years of age or older, and for patients with chronic idiopathic urticaria who are 12 years of age or older. However, omalizumab is not currently approved for treating food allergy in patients of any age.

[0032] Omalizumab is commercially available as a lyophilized powder contained in a single-use vial that is reconstituted with sterile water for injection. Omalizumab is administered by subcutaneous (SC) injection. It is also commercially available as a prefilled syringe administered by SC injection.

II. Treatment of a Human Subject Suffering From One or More Food Allergies

[0033] In the methods, uses, medicaments and kits of the present disclosure, an anti-IgE antibody, such as omalizumab, is administered to a human subject with a food allergy to one or more food allergens in an amount and/or dosing frequency to reduce or prevent an allergic reaction to consumption of the food containing the food allergen(s) by the human subject. The methods, uses, medicaments and kits of the present disclosure are contemplated to be especially valuable for pediatric patients (e.g., aged 1 year to less than 6 years) because accidental consumption is more difficult to avoid in this patient population. This is a vulnerable population where trials to assess adequacy of treatment benefit and defining safety parameters are more difficult to conduct. In some embodiments, omalizumab is to be used in conjunction with food allergen avoidance. In some embodiments, omalizumab is not indicated for the emergency treatment of allergic reactions. In some embodiments, omalizumab is not indicated for the emergency treatment of anaphylaxis.

A. Methods of Use

[0034] The present disclosure relates to methods of treating a human subject diagnosed with a food allergy to one or more food allergens with a therapeutically effective amount of omalizumab. In some embodiments, the methods of treating include preventing or reducing an allergic reaction to the one or more food allergens following exposure to or consumption by the subject. In some embodiments, the method of treating reduces the risk of an allergic reaction by the subject to exposure to or consumption of a food allergen to which the subject is allergic. In some embodiments, the method of treating reduces the severity of an allergic reaction to exposure to or consumption of a food allergen to which the subject is allergic. In some embodiments, the method of treating protects a human subject from an allergic reaction to a food allergen to which the subject is allergic.

[0035] In some embodiments, the method of treating comprises: administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of omalizumab. In some embodiments, the pharmaceutical composition of omalizumab is administered to the subject by subcutaneous injection. In some embodiments, the therapeutically effective amount of omalizumab is administered to the subject prior to exposure to or consumption of the one or more food allergens. In some embodiments, the therapeutically effective amount of omalizumab is administered to the subject prophylactically prior to consumption of the one or more food allergens. In some embodiments, the method does not comprise concurrent oral immunotherapy with the food allergen. In some embodiments, the subject is practicing food avoidance.

[0036] In some embodiments, the subject is 1 year of age or older. In some embodiments, the subject is a child from about 1 year to about 5 years of age, from about 1 year to about 4 years of age, from about 1 year to about 3 years of age, from about 1 to about 2 years of age, or is about 1 year old. In some embodiments, the subject has not received an anti-IgE therapeutic prior to the treating. In some embodiments, the subject has not received an anti-IgE therapeutic less than 6 months, less than 1 year, less than 18 months, or less than 2 years prior to the disclosed treatment.

[0037] In some embodiments of the methods described herein, the methods further comprise determining the body weight and the total serum IgE level of the subject prior to administration of the first dose of omalizumab. It is understood that a subject may gain or lose body weight during the course of treating the subject with omalizumab for a food allergy. Accordingly, the dose amount and/or frequency may change during the course of treatment. In such a scenario, the dose of omalizumab may be changed relative to the first dose and in accordance with the dosing table of **FIG. 2**, wherein a subsequent dose (any dose which is administered after the first dose) is selected based on the body weight of the subject which is determined after the first dose but prior to the subsequent dose. The selection of the dose may not include consideration of a change in serum total IgE levels from the serum total IgE levels determined no more than 4 weeks, 2 weeks, 1 week, 5 days, 4 days, 3 days, 2 days, or 24 hours prior to the first dose (e.g., the baseline serum total IgE concentration). In some embodiments, the methods of treatment further comprise determining the body weight of the subject prior to administration of a subsequent dose of omalizumab to obtain a current body weight of the subject, wherein the subsequent dose administered to the subject is based on the current body weight of the subject at a time after the first dose and prior to the subsequent

dose, and wherein the dose is based on the body weight of the subject prior to the subsequent dose and on the serum total IgE levels determined prior to the first dose of omalizumab and according to the dosing table shown in **FIG. 2**. In some embodiments, the subsequent dose is administered within 1 day, 1 week, 2 weeks, or 4 weeks of the determination of the current body weight of the subject. In some embodiments, the methods further comprise determining the age of the subject prior to administration of the first dose of omalizumab.

[0038] In some embodiments, the present disclosure further relates to methods of preventing an allergic reaction to consumption of a food allergen in a human subject with one or more food allergies, the method comprising: administering by subcutaneous injection once every two weeks to the subject a pharmaceutical composition comprising omalizumab, wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is greater than 10 kg and less than or equal to 15 kg. In some embodiments, the method does not comprise concurrent oral immunotherapy with the food allergen.

[0039] The present disclosure also relates to methods of preventing an allergic reaction to consumption of a food allergen in a human subject with one or more food allergies, the method comprising: administering by subcutaneous injection once every two to four weeks to the subject a pharmaceutical composition comprising omalizumab, wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 25 kg. In some embodiments, the method does not comprise concurrent oral immunotherapy with the food allergen.

[0040] In some embodiments, the food allergy comprises an allergy to peanut, milk, egg, wheat, cashew, hazelnut, or walnut, or a combination thereof, and the food allergen comprises peanut, milk, egg, wheat, cashew, hazelnut, or walnut, or a combination thereof. In some embodiments, the allergic reaction is a mild-to-moderate allergic reaction triggered by consumption of as little as about 100 mg to about 300 mg of the food allergen by the subject. In some embodiments, the allergic reaction is a moderate or moderate-to-severe allergic reaction triggered by consumption of as little as about 100 mg to about 300 mg of the food allergen by the subject. In some embodiments, the methods described herein permit the subject to consume a single dose of about 600 mg to about 1000 mg or more of the food allergen without triggering one or more dose-limiting symptoms or without triggering one or more moderate or severe dose-limiting symptoms. In some embodiments, the methods described herein permit the subject to consume a single dose of 100 mg, 200 mg, 300 mg,

400 mg, 500 mg, 600 mg, 700 mg, 800 mg, 900 mg, or 1000 mg of the food allergen without triggering one or more mild, moderate, and/or severe dose-limiting symptom. In some embodiments, the one or more dose-limiting symptoms comprise one or more:

skin: systemic hives, more than mild lip or face edema, pruritus causing protracted scratching, several areas of erythema pronounced erythema, and combinations thereof; and/or

respiratory: throat tightness with or without hoarseness, persistent cough, wheezing with or without dyspnea, laryngeal edema, stridor, and combinations thereof; and/or

gastrointestinal tract: moderate to severe abdominal pain, cramping, nausea, vomiting, and combinations thereof; and/or

neurological: change in mental status; and/or

circulatory: hypotension.

[0041] In some embodiments, without triggering dose-limiting symptoms in a subject treated with a dose of omalizumab comprises a lessening or lack of one or more dose-limiting symptoms. In some embodiments, without triggering dose-limiting symptoms in a subject treated with a dose of omalizumab comprises a lessening or lack of one or more moderate or severe dose-limiting symptoms.

[0042] In some embodiments of the methods described herein, the method of treatment with a therapeutically effective amount of omalizumab results in the reduction or prevention of an allergic response by a subject having a food allergy after that subject is exposed to or consumes food containing an allergen to which that subject is allergic. An allergic response can include but is not limited to several symptoms that are described in Table 1-1 as dose-limiting symptoms. These symptoms are categorized as mild, moderate, or severe. For example, a subject who has a food allergy will experience one or more symptoms described in Table 1-1 as a dose limiting response (mild, moderate, or severe) upon consumption of a food that contains the food allergen(s) to which the subject is allergic. In some embodiments, a subject who has a food allergy will experience one or more of the moderate or severe dose-limiting symptoms. Treatment according to the disclosure herein prevents an allergic reaction to a food allergen when after said treatment, the subject no longer experiences mild, moderate, and/or severe symptoms (Table 1-1). Treatment according to the disclosure herein reduces an allergic reaction to a food allergen when after said treatment, the subject experiences one or more symptoms as listed in Table 1-1 to a lesser extent level of severity than if they had not received treatment with omalizumab. In some embodiments, an expert in the field of food allergy would recognize a reduction or

prevention of an allergic reaction by omalizumab treatment as described herein. In some embodiments, an ordinarily skilled artisan would recognize a reduction or prevention of an allergic reaction by omalizumab treatment as described herein. In embodiments, the methods described herein permit the subject to consume a single dose of about 600 mg to about 1000 mg or more of the food allergen without triggering an allergic reaction or dose-limiting symptom. In some embodiments, the methods described herein permit the subject to consume a single dose of about 600 mg to about 1000 mg or more of the food allergen while reducing the severity or frequency of an allergic reaction or dose-limiting symptom.

[0043] In some embodiments, the methods of treatment described herein reduce dose-limiting symptoms a subject experiences after the subject is exposed to or consumes a food allergen to which the subject is allergic. In some embodiments, the methods reduce one or more of the dose-limiting symptoms experienced by the subject from severe to moderate, from severe to mild, or from moderate to mild. In some embodiments, the methods of treatment described herein prevent dose-limiting symptoms a subject experiences after the subject is exposed to or consumes a food allergen to which that subject is allergic. In some embodiments, the methods prevent a subject who, prior to any treatment with omalizumab, experienced severe, moderate, and/or mild dose-limiting symptoms after exposure to or consumption of an allergen to which the subject is allergic, from experiencing any severe dose-limiting symptoms, from experiencing any moderate dose-limiting symptoms, and/or from experiencing any mild dose-limiting symptoms. In some embodiments, the mild dose-limiting symptoms include limited or localized hives, swelling of the skin (e.g., mild lip edema), skin flushing (e.g., few areas of faint erythema), mild pruritus (e.g., occasional scratching), rhinorrhea (e.g., occasional sniffing or sneezing), nasal congestion, occasional cough, throat discomfort, mild abdominal (gastrointestinal) discomfort including but not limited to mild nausea with or without decreased activity, and/or isolated emesis thought to be secondary to gag. In some embodiments, the moderate dose-limiting symptoms include systemic hives (e.g., numerous or widespread hives), swelling (e.g., significant lip or face edema), pruritus causing protracted scratching, more than a few areas of erythema or pronounced erythema, throat tightness without hoarseness, persistent cough, wheezing without dyspnea, persistent moderate abdominal pain/cramping/nausea with decreased activity, and/or vomiting. In some embodiments, the severe dose-limiting symptoms include severe generalized urticarial, angioedema, and/or erythema, laryngeal edema, throat tightness

with hoarseness, wheezing with dyspnea, stridor, severe abdominal pain and/or cramping, repetitive vomiting, change in mental status, and/or clinically significant hypotension.

[0044] In some embodiments, the methods described herein reduce the allergic reaction in the subject when the subject is exposed to or consumes a food allergen to which the subject is allergic, wherein the subject, when administered a skin-prick test (SPT), experiences a wheal caused by the food allergen that is less than 4 mm, less than 3 mm, less than 2 mm, or less than 1 mm greater than a wheal caused by a saline control.

[0045] In some embodiments, the methods described herein decrease serum free IgE concentration in the subject by at least 95%, 96%, 97%, 98%, or 99% relative to serum free IgE concentration prior to the serum free IgE concentration in the subject prior to the first dose of omalizumab. In some embodiments, the decrease occurs after the first, second, third, fourth, fifth, sixth, seventh, eighth, ninth, or tenth dose of omalizumab. In some embodiments, free IgE is measured no more than 3 months, 2 months, 1 month, 2 weeks, or 1 week prior to a first dose of omalizumab. In some embodiments, free IgE in human serum is measured using a solid phase immunoenzymetric assay (IEMA).

[0046] Measurement of free IgE in the serum of a subject can be readily done, for example, according to the methods of Hamilton et al., J Immunol Methods, 303:81-91, 2005). In some embodiments, free IgE in human serum is measured using a solid phase enzyme IEMA in which IgE is captured from serum using anti-human IgE antibody and detected with labeled-FcεR1α.

[0047] In some embodiments, the methods described herein reduce the serum kilounits of allergen-specific IgE per liter (kU_A/L) in the serum of the patient. In some embodiments, the treatment reduces allergen-specific by at least 95%, 96%, 97%, 98%, or 99% relative to serum allergen-specific IgE concentration prior to the serum free IgE concentration in the subject prior to the first dose of omalizumab. In some embodiments, the decrease occurs after the first, second, third, fourth, fifth, sixth, seventh, eighth, ninth, or tenth dose of omalizumab. In some embodiments, to serum allergen-specific IgE is measured no more than 3 months, 2 months, 1 month, 2 weeks, or 1 week prior to a first dose of omalizumab. In some embodiments, to serum allergen-specific IgE in human serum is measured using an ELISA. In some embodiments, the allergen-specific IgE is peanut, milk, wheat, soy, egg, cashew, or hazelnut-specific IgE.

[0048] Measurement of allergen-specific IgE in serum can be readily done, for example, using the ThermoFisher ImmunoCAP™ specific IgE tests.

[0049] In some embodiments, the methods described herein reduce the likelihood the subject will require rescue treatment after consumption of the food allergen (e.g., a single dose of about 100 mg or more of peanut protein, and/or about 300 mg or more of milk, egg, wheat, cashew, hazelnut and/or walnut protein). In some embodiments, the rescue treatment comprises administration of an antihistamine or epinephrine. In some embodiments, the methods do not comprise concurrent oral immunotherapy to the food allergen. In other embodiments, the methods are useful in subjects who have failed prior oral immunotherapy.

[0050] In some embodiments, the disclosure provides an anti-IgE antibody for use as a medicament. In some embodiments, the anti-IgE antibody is omalizumab or a monoclonal antibody which comprises CDR-H1 (GYSITSGY, set forth as SEQ ID NO:5), CDR-H2 (TYDGS, set forth as SEQ ID NO:6), CDR-H3 (GSHYFGHWHFAV, set forth as SEQ ID NO:7), CDR-L1 (RASQSVDYDGDSYMN, set forth as SEQ ID NO:8), CDR-L2 (AASYLES, set forth as SEQ ID NO:9) and CDR-L3 (QQSHEDPYT, set forth as SEQ ID NO:10). In some embodiments the use is in the treatment of a human subject diagnosed with or having a food allergy to one or more allergens according to the embodiments described herein. In some embodiments, the use further comprises administering to the subject a pharmaceutical composition comprising a therapeutically effective amount of the anti-IgE antibody such as omalizumab, e.g., as described herein. In some embodiments, the method does not comprise treating the subject with oral immunotherapy.

[0051] In some embodiments, the disclosure provides use of an anti-IgE antibody in the manufacture or preparation of a medicament. In some embodiments, the anti-IgE antibody is omalizumab or a monoclonal antibody which comprises CDR-H1 (GYSITSGY, set forth as SEQ ID NO:5), CDR-H2 (TYDGS, set forth as SEQ ID NO:6), CDR-H3 (GSHYFGHWHFAV, set forth as SEQ ID NO:7), CDR-L1 (RASQSVDYDGDSYMN, set forth as SEQ ID NO:8), CDR-L2 (AASYLES, set forth as SEQ ID NO:9) and CDR-L3 (QQSHEDPYT, set forth as SEQ ID NO:10). In some embodiments the medicament is for treatment of a food allergy to one or more allergens. In some embodiments, the medicament is for use in a method of treating the food allergy comprising administering to an individual having the food allergy to one or more allergens a therapeutically effective amount of the medicament such as a medicament comprising omalizumab, e.g., as described herein. In

some embodiments, the method does not comprise treating the subject with oral immunotherapy.

i. Subjects

[0052] The treatment methods of the present disclosure are intended for use in human subjects. In some embodiments, the subject is 1 year of age or older. In some embodiments, the subject is a child (e.g., 1-10 years of age) or an adolescent (e.g., 11 to 18 years of age). In some embodiments, the subject is a child over 1 year of age and less than 6 years of age. In some embodiments, the child is from 1 year to 5 years of age. In some embodiments, the child is from about 1 year to about 4 years of age. In some embodiments, the child is from about 1 year to about 3 years of age. In some embodiments, the child is from about 1 year to about 2 years of age. In some embodiments, the child is about 1 year old.

[0053] In some embodiments, the subject has been identified as having a food allergy to any one or more food allergens. Food allergens may include at least one of the major food allergens identified by the United States Food and Drug Administration such as milk, eggs, fish (e.g., bass, flounder, cod), crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, soybeans and sesame. In some embodiments, the food allergen is selected from at least one of the group consisting of peanut, milk, egg, wheat, cashew, hazelnut, and/or walnut protein. In some embodiments, the food allergy comprises an allergy to at least one food allergen. In some embodiments, a food allergen is any food that causes an allergic reaction. In some embodiments, a food allergen refers to the protein in the food that causes the allergic response. In some embodiments, the one or more food allergens include but are not limited to peanut, milk, egg, wheat, cashew, hazelnut, and/or walnut protein. In some embodiments, the subject has a food allergy to peanut. In some embodiments, the subject has a food allergy to peanut, and one or more of milk, egg, wheat, cashew, hazelnut and walnut. In some embodiments, the subject has a food allergy to peanut, and two or more of milk, egg, wheat, cashew, hazelnut and walnut. In some embodiments, the subject has a food allergy to peanut, and three or more of milk, egg, wheat, cashew, hazelnut, and walnut.

[0054] In some embodiments, the subject has a food allergy to peanut, and four or more of milk, egg, wheat, cashew, hazelnut, and walnut. In some embodiments, the subject has a food allergy to peanut, and five or more of milk, egg, wheat, cashew, hazelnut, and walnut. In some embodiments, the subject has a food allergy to peanut, and milk, egg, wheat,

cashew, hazelnut, and walnut. In some embodiments, the identification comprises a diagnosis of a food allergy by a physician.

[0055] In some embodiments, the allergic reaction is characterized as a mild allergic reaction or dose-limiting symptom. As used herein a “mild” allergic reaction includes manifestations in at least one of the skin, respiratory tract and gastrointestinal system (GI tract). Mild allergic reactions may manifest in the skin as limited or localized hives, swelling (e.g., mild lip edema), skin flushing (e.g., few areas of faint erythema) or mild pruritus (e.g., occasional scratching) and the like. Mild allergic reactions may manifest in the respiratory tract as rhinorrhea (e.g., occasional sniffing or sneezing), nasal congestion, occasional cough, throat discomfort and the like. Mild allergic reactions may manifest in the GI tract as mild abdominal discomfort (including mild nausea with or without decreased activity), isolated emesis thought to be secondary to gag and the like.

[0056] In some embodiments, the allergic reaction is characterized as a moderate allergic reaction or dose-limiting symptom. As used herein a “moderate” allergic reaction includes manifestations in at least one of the skin, respiratory tract and gastrointestinal system (GI tract). Moderate allergic reactions may manifest in the skin as systemic hives (e.g., numerous or widespread hives), swelling (e.g., significant lip or face edema), pruritus causing protracted scratching, more than a few areas of erythema or pronounced erythema and the like. Moderate allergic reactions may manifest in the respiratory tract as throat tightness without hoarseness, persistent cough, wheezing without dyspnea and the like. Moderate allergic reactions may manifest in the GI tract as persistent moderate abdominal pain/cramping/nausea with decreased activity, vomiting and the like.

[0057] In some embodiments, the allergic reaction is characterized as a severe allergic reaction or dose-limiting symptom. As used herein a “severe” allergic reaction includes manifestations in at least one of the skin, respiratory tract and gastrointestinal system (GI tract). Severe allergic reactions may manifest in the skin as severe generalized urticaria/angioedema/erythema and the like. Severe allergic reactions may manifest in the respiratory tract as laryngeal edema, throat tightness with hoarseness, wheezing with dyspnea, stridor and the like. Severe allergic reactions may manifest in the GI tract as severe abdominal pain/cramping/repetitive vomiting and the like. In addition, severe allergic reaction may include neurological and circulatory manifestations such as change in mental status and clinically significant hypotension, respectively.

[0058] In embodiments, mild-to-moderate allergic reaction may be triggered by consumption of as little as about 100 mg of the food allergen by the subject prior to treatment using the disclosed methods. In embodiments, mild-to-moderate allergic reaction may be triggered by consumption of as little as about 100 mg to about 300 mg of the food allergen by the subject prior to treatment using the disclosed methods.

[0059] In some embodiments, peanut allergy is diagnosed by the presence of a clinical history of food allergy. In some embodiments the peanut allergy is diagnosed or confirmed by one or more of: i. positive skin-prick test (SPT) (equal to or greater than 4 mm wheal greater than saline control) to peanut; ii. positive peanut IgE (equal to or greater than 6 kUA/L) determined by, *e.g.*, an enzyme-linked immunosorbent assay (ELISA); and/or iii. positive blinded oral food challenge (OFC) to peanut defined as experiencing dose-limiting symptoms at a single dose of about 100 mg of peanut protein. In some embodiments, allergy to a food allergen (*e.g.*, one or more of milk, egg, wheat, cashew, hazelnut and walnut) is diagnosed by one or more of: i. positive SPT (a wheal at least 4 mm greater than saline control) to the food allergen; ii. positive food allergen-specific IgE (equal to or greater than 6 kUA/L) determined by, *e.g.*, an ELISA; and/or iii. positive blinded OFC to the food allergen defined as experiencing dose-limiting symptoms at a single dose of about 100 mg to about 300 mg of the food allergen protein. In some embodiments, the subject experiences dose-limiting symptoms to a single dose of about 100 mg of peanut protein, about 100 mg to about 300 mg protein for any two or more of milk, egg, wheat, cashew, hazelnut, and/or walnut protein, and no dose-limiting symptoms to placebo (*e.g.*, oat) at any single dose up to about 100 to about 300 mg protein prior to administration of a pharmaceutical composition comprising an anti-IgE antibody (*e.g.*, omalizumab).

[0060] In some embodiments, the subjects of the present disclosure do not have an IgE-mediated disorder that is not a food allergy (*e.g.*, the only IgE-mediated disorder the subject is known to have is a food allergy). In some embodiments, the subjects of the present disclosure do not have asthma, nasal polyps, or chronic spontaneous urticaria at initiation of the treatment methods of the present disclosure. In some embodiments, the subjects of the present disclosure have not previously been diagnosed as having asthma, nasal polyps, or chronic spontaneous urticaria. In some embodiments, the subjects do not have asthma at initiation of the prophylactic methods of the present disclosure and have not previously been diagnosed as having asthma. In some embodiments, the subject has not been diagnosed with allergic rhinoconjunctivitis. In some embodiments, the subjects of the present disclosure have

asthma, nasal polyps, or chronic spontaneous urticaria at initiation of the prophylactic methods of the present disclosure. In some embodiments, the subjects of the present disclosure have previously been diagnosed as having asthma, nasal polyps, or chronic spontaneous urticaria. In some embodiments, the subjects have asthma at initiation of the prophylactic methods of the present disclosure or have previously been diagnosed as having asthma. In some embodiments, the subject has been diagnosed with allergic rhinoconjunctivitis.

[0061] In some embodiments, the subjects of the present disclosure have not received anti-IgE therapy prior to initiation of the treatment methods of the present disclosure. In some embodiments, the subjects of the present disclosure have not received anti-IgE therapy less than 6 months, 1 year, 18 months, or 2 years prior to initiation of the treatment methods of the present disclosure.

ii. Dosing

[0062] The pharmaceutical composition is administered to the subject at a specific omalizumab dose and dosing interval based on the body weight and baseline total serum IgE concentration of the subject. The specific dose and dosing interval (frequency) is determined based on the dosing table described in **FIG. 2** herein. Accordingly, prior to administration of the pharmaceutical composition, a body weight and a baseline total serum IgE level of the subject is determined. In some embodiments, when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 25 kg and the baseline total serum IgE level is equal to or greater than 30 IU/ml and less than or equal to 2000 IU/ml, the omalizumab dose is from 75 mg to 375 mg and the dosing interval is every two to four weeks. In some embodiments, body weight is determined at baseline (prior to a first dose).

[0063] In some embodiments, body weight is determined at baseline (prior to administration of the first dose of the pharmaceutical composition). In some embodiments, total serum IgE level (concentration) is determined at baseline (prior to administration of the first dose of the pharmaceutical composition). In some embodiments, determining the baseline body weight and the baseline total serum IgE level of the subject is done no more than 3 months, 2 months, 1 month, 2 weeks, or 1 week prior to administration of a first dose of the pharmaceutical composition, preferably no more than 7, 6, 5, 4, 3, 2 or 1 day prior to administration of a first dose of the pharmaceutical composition.

[0064] In some embodiments, body weight of the subject is further determined prior to administration of a subsequent dose (post-baseline body weight) of the pharmaceutical composition. In some embodiments, the body weight is a post-baseline body weight of the subject, which is determined no more than two weeks prior to administration of each subsequent dose of the pharmaceutical composition, preferably no more than 7, 6, 5, 4, 3, 2 or 1 day prior to administration of each subsequent dose of the pharmaceutical composition. It is understood that a subject may gain or lose body weight during of the course of treating the subject with omalizumab for a food allergy. Accordingly, the dose amount and/or frequency may change during the course of treatment. In such a scenario, the dose of omalizumab may be changed relative to the first dose and in accordance with the dosing table of **FIG. 2**, wherein a subsequent dose (any dose after the first dose) is selected based on the body weight of the subject which is determined after the first dose but prior to the subsequent dose. The selection of the dose may not consider a change in serum total IgE levels from the baseline serum total IgE levels. Accordingly, in some embodiments, the methods of treatment further comprise determining the body weight of the subject prior to administration of a subsequent dose of omalizumab to obtain a current body weight of the subject, wherein the subsequent dose administered to the subject is based on the current body weight of the subject at a time after the first dose and prior to the subsequent dose, and wherein the dose is based on the body weight of the subject prior to the subsequent dose and on the serum total IgE levels determined prior to the first dose of omalizumab and according to the dosing table shown in **FIG. 2**. In some embodiments, the subsequent dose is administered within 1 day, 1 week, 2 weeks, or 4 weeks of the determination of the current body weight of the subject. In some embodiments, the methods further comprise determining the age of the subject prior to administration of the first dose of omalizumab.

[0065] In the methods and kits of the present disclosure, the body weight of the subject is from about 10 kg to about 25 kg. In the methods and kits of the present disclosure, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 25 kg. In some embodiments, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg. In some embodiments, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg.

[0066] In some embodiments, total serum IgE is measured by an enzyme-linked immunosorbent assay (ELISA). In some embodiments, the baseline total serum IgE level is equal to or greater than 30 IU/ml and less than or equal to 2000 IU/ml. In some embodiments,

the baseline total serum IgE level is from about 30 IU/ml to about 700 IU/ml. In some embodiments, the baseline total serum IgE level is from about 600 IU/ml to about 1850 IU/ml. In some embodiments, the baseline total serum IgE level is equal to or greater than 30 IU/ml and less than or equal to 1500 IU/ml. In some embodiments, the baseline total serum IgE level is from about 30 IU/ml to about 700 IU/ml. In some embodiments, the baseline total serum IgE level is from about 700 IU/ml to about 1500 IU/ml.

[0067] In certain embodiments, the dosing interval (also referred to herein as dosing frequency) is about once every 2 to 4 weeks and the duration of administration is at least 16 weeks to 12 months in length. In some embodiments, the dosing interval is every 2 weeks. In some embodiments, the dosing interval is every 4 weeks. In some embodiments, the duration of administration is at least about 16 to 20 weeks in length (*e.g.*, from 4 to 10 total doses), at least about 16 to 40 weeks (*e.g.*, from 4 to 20 total doses), or at least about 24 to 40 weeks (*e.g.*, from about 6 to 20 total doses). In some embodiments, the duration of administration is at least about 10 to 12 months in length (*e.g.*, from 10 to 24 total doses).

[0068] In some embodiments, the therapeutically effective amount of omalizumab is from about 150 mg to 300 mg, wherein prior to administration of a first dose of omalizumab to the subject, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg, and the total serum IgE level of the subject is greater than 600 IU/ml. In some embodiments, the serum total IgE level of the subject is greater than 600 IU/ml and less than or equal to 1,850 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks.

[0069] In some embodiments, the therapeutically effective amount of omalizumab is from about 375 mg to 450 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is greater than 20 kg and less than or equal to 30 kg and the serum total IgE level of the subject is greater than 1,500 IU/ml and less than or equal to 2,000 IU/ml. In some embodiments, total serum IgE level of the subject is greater than 1,500 IU/ml and less than or equal to 1,850 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks.

[0070] In some embodiments, the therapeutically effective amount of omalizumab is from about 150 mg to 225 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than

or equal to 2,000 IU/ml. In some embodiments, total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1,850 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks.

[0071] In some embodiments, the therapeutically effective amount of omalizumab is from about 75 mg to 150 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is greater than 10 kg and less than or equal to 15 kg and the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 600 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 4 weeks. In some embodiments, the subject is a child of from 1 year to 4 years of age, from 1 year to 3 years of age, from 1 to 2 years of age, or is about 1 year old.

[0072] In some embodiments, the therapeutically effective amount of omalizumab is from about 75 mg to 225 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is greater than 15 kg and less than or equal to 20 kg and the serum total IgE level of the subject is greater than 30 IU/ml and less than 700 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 4 weeks.

[0073] In some embodiments, the therapeutically effective amount of omalizumab is from about 75 mg to 300 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is greater than 20 kg and less than or equal to 25 kg and the serum total IgE level of the subject is greater than 30 IU/ml and less than 700 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 4 weeks.

[0074] In some embodiments, the therapeutically effective amount of omalizumab is from about 75 mg to 300 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is greater than 20 kg and less than or equal to 30 kg and the serum total IgE level of the subject is greater than 30 IU/ml and less than 600 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 4 weeks.

[0075] In some embodiments, the therapeutically effective amount of omalizumab is from about 150 mg to 300 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is greater than 15 kg and less than or equal to 25 kg and the serum total IgE level of the subject is greater than 700 IU/ml and less than 2000

IU/ml. In some embodiments, total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1,850 IU/ml. In some embodiments, total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1,500 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks.

[0076] In some embodiments, the therapeutically effective amount of omalizumab is from about 225 mg to 375 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is greater than 25 kg and less than or equal to 30 kg and the serum total IgE level of the subject is greater than 600 IU/ml and less than 2000 IU/ml. In some embodiments, total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1,850 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks.

[0077] In some embodiments, the therapeutically effective amount of omalizumab is from about 75 mg to 375 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 25 kg, and the total serum IgE level of the subject is equal to or greater than about 30 IU/ml and less than or equal to about 1850 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks or 4 weeks. In some embodiments, the age of the subject is from 1 to 4 years.

[0078] In some embodiments, the therapeutically effective amount of omalizumab is from about 150 mg to 450 mg, wherein prior to administration to the subject of a first dose of omalizumab, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 30 kg, and the total serum IgE level of the subject is greater than about 1500 IU/ml and less than or equal to about 1850 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks.

[0079] In some embodiments, the therapeutically effective amount of omalizumab is from 75 mg to 150 mg omalizumab, wherein prior to administration to the subject of a first dose of omalizumab, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is equal to or greater than about 30 IU/ml and less than or equal to about 1500 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks or 4 weeks.

[0080] In some embodiments, the therapeutically effective amount of omalizumab is from 150 mg to 300 mg, wherein prior to administration to the subject of a first dose of

omalizumab, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg, and the total serum IgE level of the subject is equal to or greater than about 30 and less than or equal to about 1850 IU/ml. In some embodiments, the dose of omalizumab is administered to the subject every about 2 weeks.

[0081] In some embodiments, the therapeutically effective amount of omalizumab is 75 mg, wherein the body weight of the subject is greater than or equal to 10 kg and less than or equal to 15 kg, and the total serum IgE of the subject is greater than or equal to 30 IU/ml and less than or equal to 300 IU/ml; the body weight of the subject is greater than or equal to 10 kg and less than or equal to 20 kg, and the total serum IgE of the subject is greater than or equal to 30 IU/ml and less than or equal to 200 IU/ml; the body weight of the subject is greater than or equal to 10 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than or equal to 30 IU/ml and less than or equal to 100 IU/ml; the body weight of the subject is greater than 15 kg and less than or equal to 20 kg, and the total serum IgE of the subject is greater than or equal to 30 IU/ml and less than or equal to 200 IU/ml; or the body weight of the subject is greater than 20 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than or equal to 30 IU/ml and less than or equal to 100 IU/ml; and wherein the dose is administered every 4 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab.

[0082] In some embodiments, the therapeutically effective amount of omalizumab is 150 mg, wherein the body weight of the subject is greater than or equal to 10 kg and less than or equal to 12 kg, and the total serum IgE of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; the body weight of the subject is greater than or equal to 10 kg and less than or equal to 15 kg, and the total serum IgE of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; the body weight of the subject is greater than 15 kg and less than or equal to 20 kg, and the total serum IgE of the subject is greater than 200 IU/ml and less than or equal to 400 IU/ml; the body weight of the subject is greater than 15 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than 200 IU/ml and less than or equal to 300 IU/ml; or the body weight of the subject is greater than 20 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than 100

IU/ml and less than or equal to 300 IU/ml; and wherein the dose is administered every 4 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab.

[0083] In some embodiments, the therapeutically effective amount of omalizumab is 225 mg, wherein the body weight of the subject is greater than 15 kg and less than or equal to 20 kg, and the total serum IgE of the subject is greater than 400 IU/ml and less than or equal to 700 IU/ml; the body weight of the subject is greater than 15 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than 400 IU/ml and less than or equal to 500 IU/ml; or the body weight of the subject is greater than 20 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than 300 IU/ml and less than or equal to 500 IU/ml; and wherein the dose is administered every 4 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab. In some embodiments, the therapeutically effective amount of omalizumab is 300 mg, wherein the body weight of the subject is greater than 20 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than 500 IU/ml and less than or equal to 700 IU/ml; and wherein the dose is administered every 4 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab. In some embodiments, the therapeutically effective amount of omalizumab is 150 mg, wherein the body weight of the subject is greater than or equal to 10 kg and less than or equal to 12 kg, and the total serum IgE of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or the body weight of the subject is greater than 15 kg and less than or equal to 20 kg, and the total serum IgE of the subject is greater than 700 IU/ml and less than or equal to 900 IU/ml; and wherein the dose is administered every 2 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab.

[0084] In some embodiments, the therapeutically effective amount of omalizumab is 225 mg, wherein the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; the body weight of the subject is greater than 15 kg and less than or equal to 20 kg, and the total serum IgE of the subject is greater than 900 IU/ml and less than or equal to 1300 IU/ml; or the body weight of the subject is greater than 20 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than 700 IU/ml and less than or equal to 1100 IU/ml; and wherein the dose is administered every 2 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab.

[0085] In some embodiments, the therapeutically effective amount of omalizumab is 300 mg, wherein the body weight of the subject is greater than 15 kg and less than or equal to 20 kg, and the total serum IgE of the subject is greater than 1300 IU/ml and less than or equal to 1850 IU/ml; or the body weight of the subject is greater than 20 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than 1100 IU/ml and less than or equal to 1500 IU/ml; and wherein the dose is administered every 2 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab.

[0086] In some embodiments, the therapeutically effective amount of omalizumab is 375 mg, wherein the body weight of the subject is greater than 20 kg and less than or equal to 25 kg, and the total serum IgE of the subject is greater than 1500 IU/ml and less than or equal to 1850 IU/ml; and wherein the dose is administered every 2 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab. In some embodiments, the therapeutically effective amount of omalizumab is 450 mg, wherein the body weight of the subject is greater than 25 kg and less than or equal to 30 kg, and the total serum IgE of the subject is greater than 1500 IU/ml and less than or equal to 1850 IU/ml; and wherein the dose is administered every 2 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the

body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab.

[0087] In some embodiments, the therapeutically effective amount of omalizumab is 600 mg, wherein the body weight of the subject is greater than 30 kg and less than or equal to 40 kg, and the total serum IgE of the subject is greater than 1500 IU/ml and less than or equal to 1850 IU/ml; and wherein the dose is administered every 2 weeks. In some embodiments the body weight of the subject is determined prior to administration of the dose of omalizumab. In some embodiments, the body weight and total serum IgE of the subject are determined prior to administration of a first dose of omalizumab.

[0088] In some embodiments, the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of ≥ 30 -100 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of > 100 -200 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of > 200 -300 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of > 300 -400 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of > 400 -500 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of > 500 -600 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of > 600 -700 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of > 700 -800 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of > 800 -900 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of > 900 -1000 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of > 1000 -1100 IU/ml and a body

weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1100 -1200 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1200 -1300 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1300 -1500 IU/ml and a body weight of ≥ 10 -12 kg. In some embodiments, the subject is not dosed when the subject has a baseline total serum IgE of or >1500 -1850 IU/ml or >1500 -1850 IU/ml and a body weight of ≥ 10 -12 kg.

[0089] In some embodiments, the body weight of the subject is greater than 12 kg and less than or equal to 15 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of ≥ 30 -100 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >100 -200 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >200 -300 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >300 -400 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >400 -500 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >500 -600 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >600 -700 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >700 -800 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >800 -900 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >900 -1000 IU/ml and a body weight of >12 -15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1000 -1100 IU/ml and a body

weight of >12-15 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1100-1200 IU/ml and a body weight of >12-15 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1200-1300 IU/ml and a body weight of >12-15 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1300-1500 IU/ml and a body weight of >12-15 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of or >1500-1850 IU/ml or >1500-1850 IU/ml and a body weight of >12-15 kg.

[0090] In some embodiments, the body weight of the subject is greater than 15 kg and less than or equal to 20 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >30-100 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >100-200 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >200-300 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >300-400 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >400-500 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >500-600 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >600-700 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >700-800 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >800-900 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >900-1000 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1000-1100 IU/ml and a body

weight of >15-20 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1100-1200 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1200-1300 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 300 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1300-1500 IU/ml and a body weight of >15-20 kg. In some embodiments, the dose is 300 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of or >1500-2000 IU/ml >1500-1850 IU/ml and a body weight of >15-20 kg.

[0091] In some embodiments, the body weight of the subject is greater than 20 kg and less than or equal to 25 kg. In some embodiments, the dose is 75 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >30-100 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >100-200 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 150 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >200-300 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >300-400 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >400-500 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 300 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >500-600 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 300 mg, and the dosing frequency is every four weeks when the subject has a baseline total serum IgE of >600-700 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >700-800 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >800-900 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >900-1000 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 225 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1000-1100 IU/ml and a body

weight of >20-25 kg. In some embodiments, the dose is 300 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1100-1200 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 300 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1200-1300 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 300 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1300-1500 IU/ml and a body weight of >20-25 kg. In some embodiments, the dose is 375 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1500-1850 IU/ml or >1500-1850 IU/ml and a body weight of >20-25 kg.

[0092] In some embodiments, the body weight of the subject is greater than 25 kg and less than or equal to 30 kg. In some embodiments, the dose is 450 mg, and the dosing frequency is every two weeks when the subject has a baseline total serum IgE of >1500-2000 IU/ml or >1500-1850 IU/ml and a body weight of >25-30 kg.

iii. Route and Duration of Administration

[0093] The pharmaceutical compositions of the present disclosure comprising an anti-IgE antibody, such as omalizumab, are administered by subcutaneous injection to a human subject diagnosed with or suffering from one or more food allergies.

[0094] The methods of the present disclosure may include repeated administration of the pharmaceutical composition comprising an anti-IgE antibody, such as omalizumab. In some embodiments, the duration of administration is until the subject is no longer diagnosed with food allergy. In some embodiments, the duration of treating is at least 16 to 20 weeks in length. In some embodiments, the duration of treating is at least 40 to 48 weeks in length. In some embodiments, the duration of treating is at least about 10 months to about 12 months in length. For example, in some embodiments, the duration of treating can be at least about 16 weeks, 18 weeks, 20 weeks, 22 weeks, 24 weeks, 26 weeks, 28 weeks, 30 weeks, 32 weeks, 34 weeks, 36 weeks, 38 weeks, or 40 weeks. In some embodiments, the duration of treating can be at least about 6 months, 8 months, about 10 months, or 12 months.

B. Kits

[0095] The present disclosure also provides kits for use in the methods described above. In some embodiments, the kits, comprise: i) a pharmaceutical composition comprising an anti-IgE antibody, such as omalizumab; and ii) instructions for administration of the pharmaceutical composition by subcutaneous injection to a human subject suffering from one or more food allergies to prevent an allergic reaction triggerable by consumption of a food allergen by the human subject, wherein the pharmaceutical composition is administered at an anti-IgE antibody (e.g., omalizumab) dose and a dosing interval determined from measurement of body weight and baseline total serum IgE level of the subject. In some embodiments, the pharmaceutical composition is an aqueous solution further comprising L-arginine hydrochloride, L-histidine, and L-histidine hydrochloride monohydrate. In some embodiments, the pharmaceutical composition further comprises sucrose. In specific embodiments, the pharmaceutical composition contains omalizumab at a concentration of about 150 g/L in 0.02 M histidine, 0.2 M arginine-HCl, and 0.04 % polysorbate 20, pH 6. In some embodiments, the pharmaceutical composition is present in a pre-filled syringe. In some embodiments, the pharmaceutical composition is a lyophilized powder present in a vial, and the kit further comprises instructions for reconstituting the lyophilized powder in water for injection.

III. Enumerated Embodiments

1. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:
 administering by subcutaneous injection to the subject once about every two weeks a pharmaceutical composition comprising omalizumab at a dose of from 150 mg to 300 mg,
 wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml.
2. The method of embodiment 1, wherein the dose of omalizumab administered about every two weeks is:
 150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml; or
 150 mg when the body weight of the subject is greater than 12 kg and less than or equal to

15 kg and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

150 mg when the body weight of the subject is greater than 15 kg and less than or equal to 20 kg and the total serum IgE level of the subject is greater than 700 IU/ml and less than or equal to 900 IU/ml.

3. The method of embodiment 1, wherein the dose of omalizumab administered about every two weeks is:

225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 2000 IU/ml; or

225 mg when the body weight of the subject is greater than 15 kg and less than or equal to 20 kg and the total serum IgE level of the subject is greater than 900 IU/ml and less than or equal to 1300 IU/ml.

4. The method of embodiment 1, wherein the dose of omalizumab administered about every two weeks is:

300 mg when the body weight of the subject is greater than 15 kg and less than or equal to 20 kg and the total serum IgE level of the subject is greater than 1300 IU/ml and less than or equal to 2000 IU/ml.

5. The method of any one of embodiments 1-5, wherein the subject is from 1 year to 5 years of age, optionally wherein the subject is from about 1 year to 4 years of age, or from about 1 year to 3 years of age, or about 1 year or about 2 years of age.

6. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection to the subject once about every two weeks a pharmaceutical composition comprising omalizumab at a dose of from 375 mg to 450 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is greater than 20 kg and less than or equal to 30 kg and total serum IgE level of the subject is greater than 1,500 IU/ml and less than or equal to 2,000 IU/ml.

7. The method of embodiment 6, wherein the body weight of the subject is greater than 20 kg and less than or equal to 25 kg.

8. The method of embodiment 7, wherein the dose of omalizumab administered about every two weeks is 375 mg.

9. The method of embodiment 6, wherein the body weight of the subject is greater than 25 kg and less than or equal to 30 kg.
10. The method of embodiment 9, wherein the dose of omalizumab administered about every two weeks is 450 mg.
11. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:
 - administering by subcutaneous injection to the subject once about every two weeks a pharmaceutical composition comprising omalizumab at a dose of from 150 mg to 225 mg,
 - wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml.
12. The method of embodiment 11, wherein the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg.
13. The method of embodiment 12, wherein the dose of omalizumab administered about every two weeks is 150 mg.
14. The method of embodiment 13, wherein the total serum IgE level of the subject is greater than 700 IU/ml and less than or equal to 1,500 IU/ml.
15. The method of embodiment 11, wherein the body weight of the subject is greater than 12 kg and less than or equal to 15 kg.
16. The method of embodiment 15, wherein the dose of omalizumab administered about every two weeks is 150 mg when the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1,200 IU/ml.
17. The method of embodiment 16, wherein the total serum IgE level of the subject is greater than 700 IU/ml and less than or equal to 1,200 IU/ml.
18. The method of embodiment 15, wherein the dose of omalizumab administered about every two weeks is 225 mg when the total serum IgE level of the subject is greater than 1,200 IU/ml and less than or equal to 2,000 IU/ml.
19. The method of any one of embodiments 11-18, wherein the subject is from 1 year to 5 years of age.

20. The method of embodiment 19, wherein the subject is from 1 year to 4 years of age, optionally wherein the subject is from 1 year to 3 years of age.

21. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection to the subject once about every four weeks a pharmaceutical composition comprising omalizumab at a dose of from 75 mg to 150 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 600 IU/ml.

22. The method of embodiment 21, wherein the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg.

23. The method of embodiment 22, wherein the dose of omalizumab administered once about every four weeks is 75 mg when the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml.

24. The method of embodiment 22, wherein the dose of omalizumab administered once about every four weeks is 150 mg when the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml.

25. The method of embodiment 21, wherein the body weight of the subject is greater than 12 kg and less than or equal to 15 kg.

26. The method of embodiment 25, wherein the dose of omalizumab administered once about every four weeks is 75 mg when the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml.

27. The method of embodiment 25, wherein the dose of omalizumab administered once about every four weeks is 150 mg when the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml.

28. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection to the subject once about every two weeks a pharmaceutical composition comprising a therapeutically effective amount omalizumab,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg.

29. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection to the subject once about every two to four weeks a pharmaceutical composition comprising a therapeutically effective amount omalizumab,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 25 kg.

30. The method of embodiment 28 or embodiment 29, wherein the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg.

31. The method of embodiment 28 or embodiment 29, wherein the body weight of the subject is greater than 12 kg and less than or equal to 15 kg.

32. The method of embodiment 29, wherein the body weight of the subject is greater than 15 kg and less than or equal to 20 kg.

33. The method of embodiment 29, wherein the body weight of the subject is greater than 20 kg and less than or equal to 25 kg.

34. The method of embodiment 30 or embodiment 31, wherein total serum IgE level of the subject prior to administration of the first dose of omalizumab is greater than 600 IU/ml and less than or equal to 2,000 IU/ml.

35. The method of any one of embodiments 30-33, wherein the total serum IgE level of the subject prior to administration of the first dose of omalizumab is greater than 1,500 IU/ml and less than or equal to 1,850 IU/ml.

36. The method of any one of embodiments 1-35, wherein the subject has not been diagnosed with allergic rhinoconjunctivitis prior to administration of the first dose of omalizumab.

37. The method of any one of embodiments 1-36, wherein the subject has not been diagnosed with asthma, nasal polyps, or chronic spontaneous urticaria prior to administration of the first dose of omalizumab.

38. The method of any one of embodiments 1-37, wherein the food allergy comprises an allergy to one or more food allergens selected from the group consisting of peanut, milk, egg, wheat, cashew, hazelnut, or walnut, and a combination thereof.

39. The method of embodiment 38, wherein the food allergy comprises an allergy to two or more food allergens selected from the group consisting of peanut, milk, egg, wheat, cashew, hazelnut, or walnut, and a combination thereof.

40. The method of embodiment 38, wherein the food allergy comprises an allergy to peanut and an allergy to two or more food allergens selected from milk, egg, wheat, cashew, hazelnut and walnut.

41. The method of embodiment 40, wherein the subject was identified as having food allergy to multiple food allergens prior to the administering step according to criteria comprising:

a) a skin-prick test resulting in a wheal of at least 4 mm in diameter to peanut and two or more of milk, egg, wheat, cashew, hazelnut and walnut; and/or

b) a peanut IgE level of at least 6 kUA/L and an IgE level of at least 6 kUA/L to two or more allergens selected from milk, egg, wheat, cashew, hazelnut and walnut; and/or

c) development of a moderate-to-severe allergic reaction after consumption of about 100 mg or from 10 mg to 100 mg of peanut protein, and/or consumption of about 300 mg or from 30mg to 300 mg of milk, egg, wheat, cashew, hazelnut and/or walnut protein.

42. The method of any one of embodiments 1-40, wherein the allergic reaction is a moderate-to-severe allergic reaction.

43. The method of embodiment 42, wherein the moderate-to-severe allergic reaction to a food comprises onset of one or more symptoms after consumption of about 100 mg or from 10 mg to 100 mg of peanut protein, and/or consumption of about 300 mg or from 30 mg to 300 mg of milk, egg, wheat, cashew, hazelnut and/or walnut protein, and wherein the one or more symptoms comprise one or more:

skin: systemic hives, more than mild lip or face edema, pruritus causing protracted scratching, several areas of erythema pronounced erythema, and combinations thereof; and/or

respiratory: throat tightness with or without hoarseness, persistent cough, wheezing with or without dyspnea, laryngeal edema, stridor, and combinations thereof; and/or

gastrointestinal tract: moderate to severe abdominal pain, cramping, nausea, vomiting, and combinations thereof; and/or

neurological: change in mental status; and/or

circulatory: hypotension.

44. The method of any one of embodiments 1-43, wherein preventing the allergic reaction permits the subject to consume a single dose of about 600 mg or from 600 mg to 1800 mg of peanut protein, and/or a single dose of about 1000 mg or from 1000 mg to 3000 mg of milk, egg, wheat, cashew, hazelnut and/or walnut protein without triggering dose-limiting symptoms.

45. The method of any one of embodiments 1-43, wherein preventing the allergic reaction permits the subject to consume a single dose of about 1000 mg or from 1000 mg to 3000 mg of peanut, milk, egg, wheat, cashew, hazelnut and/or walnut protein without triggering dose-limiting symptoms.

46. The method of any one of embodiments 1-43, wherein preventing the allergic reaction permits the subject to consume a single dose of about 2000 mg or from 2000 mg to 6000 mg of peanut, milk, egg, wheat, cashew, hazelnut and/or walnut protein without triggering dose-limiting symptoms.

47. The method of any one of embodiments 1-43, wherein preventing the allergic reaction reduces likelihood that the subject will require treatment with antihistamine or epinephrine after consuming a single dose of about 100 mg or from 100 mg to 300 mg of peanut protein, and/or a single dose of about 300 mg or from 300 mg to 900 mg of milk, egg, wheat, cashew, hazelnut and/or walnut protein.

48. The method of any one of embodiments 1-47, further comprising determining the body weight and the total serum IgE level of the subject prior to administration of the first dose of omalizumab.

49. The method of embodiment 48, wherein determining the body weight and the total serum IgE level of the subject is done one within month prior to administration of the first dose of omalizumab.

50. The method of embodiment 49, wherein determining the body weight and the total serum IgE level of the subject is done two weeks prior to administration of the first dose of omalizumab.

51. The method of any one of embodiments 1-50, wherein duration of the administering step is at least 16 to 20 weeks in length.

52. The method of any one of embodiments 1-50, wherein duration of the administering step is at least 10 to 12 months in length.

53. The method of any one of embodiments 48-52, wherein determining the total serum IgE level is done with an enzyme-linked immunosorbent assay.
54. The method of any one of embodiments 1-53, wherein the pharmaceutical composition is an aqueous solution further comprising L-arginine hydrochloride, L-histidine, and L-histidine hydrochloride monohydrate.
55. The method of embodiment 54, wherein the pharmaceutical composition further comprises sucrose.
56. The method of any one of embodiments 1-55, wherein the method prevents or reduces allergic reaction in the subject following consumption of food containing the one or more food allergens.
57. The method of any one of embodiments 1-56, wherein the method does not comprise concurrent oral immunotherapy with the one or more food allergens.
58. A kit comprising:
- i) a pharmaceutical composition comprising omalizumab; and
 - ii) instructions for administering the pharmaceutical composition according to the method of any one of embodiments 1-57.
59. The kit of embodiment 58, wherein the pharmaceutical composition is an aqueous solution present in a prefilled syringe.
60. The kit of embodiment 58, wherein the pharmaceutical composition is lyophilized powder present in a vial and the kit further comprises sterile water for injection and instructions for reconstitution of the powder with the sterile water.
61. The kit of embodiment 60, wherein the kit further comprises a syringe and a needle for subcutaneous injection of the pharmaceutical composition.
62. Omalizumab for use in a method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:
- administering by subcutaneous injection once every two weeks to the subject a pharmaceutical composition comprising omalizumab at a dose of from 150 mg to 300 mg, wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml, and

wherein the method does not comprise concurrent oral immunotherapy with the food allergen.

63. Omalizumab for use in a method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection once every two weeks to the subject a pharmaceutical composition comprising omalizumab at a dose of from 375 mg to 450 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 20 kg and less than or equal to 30 kg and total serum IgE level of the subject is greater than 1,500 IU/ml and less than or equal to 2,000 IU/ml, and

wherein the method does not comprise concurrent oral immunotherapy with the food allergen.

64. Omalizumab for use in a method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection once every two weeks to the subject a pharmaceutical composition comprising omalizumab at a dose of from 150 mg to 225 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml, and

wherein the method does not comprise concurrent oral immunotherapy with the food allergen.

65. Omalizumab for use in a method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection once every four weeks to the subject a pharmaceutical composition comprising omalizumab at a dose of from 75 mg to 150 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 600 IU/ml, and

wherein the method does not comprise concurrent oral immunotherapy with the food allergen.

66. Use of omalizumab at a dose of from 150 mg to 300 mg in the manufacture of a medicament for treating a human subject diagnosed with a food allergy to one or more food

allergens, wherein the medicament is to be administered by subcutaneous injection once every two weeks to the subject when prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml, and wherein the medicament is not administered in combination with oral immunotherapy with the food allergen.

67. Use of omalizumab at a dose of from 375 mg to 450 mg in the manufacture of a medicament for treating a human subject diagnosed with a food allergy to one or more food allergens, wherein the medicament is to be administered by subcutaneous injection once every two weeks to the subject when prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 20 kg and less than or equal to 30 kg and total serum IgE level of the subject is greater than 1,500 IU/ml and less than or equal to 2,000 IU/ml, and wherein the medicament is not administered in combination with oral immunotherapy with the food allergen.

68. Use of omalizumab at a dose of from 150 mg to 225 mg in the manufacture of a medicament for treating a human subject diagnosed with a food allergy to one or more food allergens, wherein the medicament is to be administered by subcutaneous injection once every two weeks to the subject when prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml, and wherein the medicament is not administered in combination with oral immunotherapy with the food allergen.

69. Use of omalizumab at a dose of from 75 mg to 150 mg in the manufacture of a medicament for treating a human subject diagnosed with a food allergy to one or more food allergens, wherein the medicament is to be administered by subcutaneous injection once every four weeks to the subject when prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 600 IU/ml, and wherein the medicament is not administered in combination with oral immunotherapy with the food allergen.

70. A method of treating a human subject diagnosed with a food allergy to one or more food allergens selected from the group consisting of peanut, cashew, milk and egg proteins,

the method comprising administering to the human subject an effective amount of omalizumab by subcutaneous injection once every two or four weeks,

wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of at least about 3 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 600 mg of peanut protein, and/or a single dose of about 1000 mg of cashew protein, and/or a single dose of about 1000 mg milk protein, and/or a single dose of about 1000 mg egg protein, optionally wherein the OR is from about 3 to about 900, or wherein the OR is from about 15 to about 45.

71. The method of embodiment 70, wherein the plurality of human subjects have a food allergy to peanut protein, and wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of from about 10 to about 200 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 600 mg of peanut protein, optionally wherein the OR is from about 30 to about 40, or wherein the OR is about 37.

72. The method of embodiment 70, wherein the plurality of human subjects have a food allergy to cashew protein, and wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of from about 3 to about 900 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 1000 mg of cashew protein, optionally wherein the OR is from about 15 to about 25, or wherein the OR is about 21.

73. The method of embodiment 70, wherein the plurality of human subjects have a food allergy to milk protein, and wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of from about 3 to about 160 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 1000 mg of milk protein, optionally wherein the OR is from about 10 to about 20, or wherein the OR is about 16.

74. The method of embodiment 70, wherein the plurality of human subjects have a food allergy to egg protein, and wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of at least about 10 for preventing development of dose-limiting symptoms after the human subjects consume

a single dose of about 1000 mg of egg protein,
optionally wherein the OR is at least about 100, 1,000, 10,000, 100,000, or 1,000,000.

75. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering to the subject an anti-IgE antibody at a dose of from 75 mg to 300 mg,
wherein the subject has a body weight equal to or greater than about 10 kg and less than or equal to about 20 kg, and the subject has a total serum IgE level equal to or greater than about 30 IU/ml.

76. The method of embodiment 75, wherein the anti-IgE antibody is omalizumab.

77. The method of embodiment 75, wherein the omalizumab is administered as a pharmaceutical composition comprising omalizumab.

78. The method of any one of embodiments 75 to 77, wherein the subject has a total serum IgE level equal to or greater than about 30 IU/ml and less than or equal to about 2,000 IU/ml.

79. The method of any one of embodiments 75 to 78, wherein each dose of anti-IgE antibody administered to the subject is determined prior to administration of the first dose of the anti-IgE antibody.

80. The method of any one of embodiments 75 to 79, wherein the subject has a total serum IgE level of equal to or greater than about 30 IU/ml and less than or equal to about 2,000 IU/ml prior to administration of the first dose of the anti-IgE antibody.

81. The method any one of embodiments 75 to 80, wherein the subject has a body weight equal to or greater than about 10 kg and less than or equal to about 20 kg prior to administration of the first dose of the anti-IgE antibody.

82. The method of any one of embodiments 75 to 81, wherein the dose of anti-IgE antibody is administered to the subject every two or four weeks.

83. The method of any one of embodiments 75 to 82, wherein the dose of anti-IgE antibody is

(i) 75 mg every 4 weeks if the subject has

a body weight of ≥ 10 -15 kg, and total serum IgE level of ≥ 30 -300 IU/ml, or

a body weight of ≥ 10 -20 kg, and total serum IgE level of ≥ 30 -200 IU/ml;

(ii) 150 mg every 4 weeks if the subject has

- a body weight of ≥ 10 -15 kg, and total serum IgE level of >300-600 IU/ml,
- a body weight of ≥ 10 -20 kg, and total serum IgE level of >300-400 IU/ml, or
- a body weight of >15-20 kg, and total serum IgE level of >200-400 IU/ml;
- (iii) 225 mg every 4 weeks if the subject has
 - a body weight of >15-20 kg, and total serum IgE level of >400-700 IU/ml;
- (iv) 150 mg every 2 weeks if the subject has
 - a body weight of ≥ 10 -12 kg, and total serum IgE level of >600-1500 IU/ml,
 - a body weight of >12-15 kg, and total serum IgE level of >600-1200 IU/ml,
 - a body weight of ≥ 10 -15 kg, and total serum IgE level of >600-1200 IU/ml, or
 - a body weight of ≥ 10 -20 kg, and total serum IgE level of >700-900 IU/ml;
- (v) 225 mg every 2 weeks if the subject has
 - a body weight of >12-15 kg, and total serum IgE level of >1200-1850 IU/ml, or
 - a body weight of >15-20 kg, and total serum IgE level of >900-1300 IU/ml; and
- (vi) 300 mg every 2 weeks if the subject has
 - a body weight of >15-20 kg, and total serum IgE level of >1300-1850 IU/ml.

84. The method of any one of embodiments 75 to 83, wherein the dose of anti-IgE antibody is administered to the subject subcutaneously or intravenously.

85. The method of embodiment 84, wherein the dose of anti-IgE antibody is administered to the subject subcutaneously.

86. The method of embodiment 85, wherein the dose of anti-IgE antibody is administered to the subject by subcutaneous injection.

87. The method of any one of embodiments 75 to 86, wherein the dose of anti-IgE antibody is administered to the subject until said subject is no longer diagnosed with food allergy.

88. The method of any one of embodiments 75 to 87, wherein the subject is diagnosed with food allergy to more than one food allergen.

89. The method of any one of embodiments 75 to 88, wherein the food allergen comprises peanut protein.

90. The method of any one of embodiments 75 to 89, wherein the subject is greater than 1 year and less than 6 years of age.

91. The method of any one of embodiments 75 to 90, wherein the dose of anti-IgE antibody is not administered in combination with oral immunotherapy with the food allergen.
92. The method any one of embodiments 75 to 91, wherein the incidence of allergic reaction to the food allergen is reduced.
93. The method any one of embodiments 75 to 91, wherein the severity of allergic reaction to the food allergen is reduced.
94. The method any one of embodiments 75 to 91, wherein allergic reaction to the food allergen is prevented.

EXAMPLES

[0096] In the experimental disclosure which follows, the following abbreviations apply: Ab (antibody); AE (adverse event); DBPCFC (double-blind placebo-controlled oral food challenge); ELISA (enzyme-linked immunosorbent assay); IEMA (immunoenzymetric assay); IgE (immunoglobulin E); IU (international units); mAb (monoclonal antibody); OFC (oral food challenge); OIT (oral immunotherapy); OLE (open-label extension); QoL (quality of life), SOC (system organ classes); and TEAE (treatment-emergent AE).

EXAMPLE 1

Treatment of Patients with Multiple Food Allergies with Omalizumab

[0097] This Example describes Screening, Stage 1, and Stage 1 Open-Label Extension (OLE) of a 3-stage Phase 3 clinical study (OUtMATCH) to test use of omalizumab for treatment of human subjects having allergies to one or more foods. Stage 1 is directed to use of omalizumab as a monotherapy to treat food allergy patients, i.e., without receiving oral immunotherapy and while practicing food avoidance. A flow chart of Stage 1 of the study design is shown in **FIG. 1**, which details the screening stage using oral food challenges, Stage 1 employing treatment and re-testing with oral food challenges and Stage 1 OLE employing continued treatment and re-testing with oral food challenges.

[0098] The study was open to children and adults (1 to 55 years of age) who are allergic to peanut and at least two other foods (selected from milk, egg, wheat, cashew, hazelnut, and walnut) to evaluate the ability of subjects to consume foods without dose-limiting symptoms (described below in **Table 1-1**) during a double-blind placebo-controlled food challenge (DBPCFC; Sampson, Ann Allergy, 60:262-269, 1988) after treatment with either omalizumab or placebo.

Table 1-1. Dose-limiting Symptoms

Severity	Symptoms
Mild	<p>Skin: limited or localized hives, swelling (e.g., mild lip edema), skin flushing (e.g., few areas of faint erythema) or mild pruritus (e.g., occasional scratching).</p> <p>Respiratory: rhinorrhea (e.g., occasional sniffing or sneezing), nasal congestion, occasional cough, throat discomfort.</p> <p>GI: mild abdominal discomfort (including mild nausea with or without decreased activity), isolated emesis thought to be secondary to gag.</p>
Moderate	<p>Skin: systemic hives (e.g., numerous or widespread hives), swelling (e.g., significant lip or face edema), pruritus causing protracted scratching, more than a few areas of erythema or pronounced erythema.</p> <p>Respiratory: throat tightness without hoarseness, persistent cough, wheezing without dyspnea.</p> <p>GI: persistent moderate abdominal pain/cramping/nausea with decreased activity, vomiting.</p>
Severe	<p>Skin: severe generalized urticaria/angioedema/erythema.</p> <p>Respiratory: laryngeal edema, throat tightness with hoarseness, wheezing with dyspnea, stridor.</p> <p>GI: severe abdominal pain/cramping/repetitive vomiting.</p> <p>Neurological: change in mental status.</p> <p>Circulatory: clinically significant hypotension</p>

[0099] A summary of the Stage 1 study, Stage 1 study protocol, and Stage 1 study results of an interim analysis in 165 pediatric patients (age $\geq$ 1 year and $<$ 18 years of age) is described below.

[0100] *Stage 1:* Participants were those who experienced dose-limiting symptoms after receiving a single dose of $\leq$ 100 mg of peanut protein and $\leq$ 300 mg protein for each of the other two foods, or those who experienced no dose-limiting symptoms after receiving placebo at any single dose up to 300 mg protein during the Screening DBPCFC were randomized 2:1 to 16-20 weeks of treatment with omalizumab or placebo for omalizumab per the omalizumab dosing table of **FIG. 2**. After 16-20 weeks of treatment, each participant completed a DBPCFC consisting of placebo and each of their three specific foods to a cumulative dose of 6044 mg protein of each food.

[0101] *Stage 1 Open-Label Extension (OLE):* The first 60 participants who completed Stage 1 were selected to participate in the OLE. Each participant received 24-28 weeks of

open label omalizumab. After 24-28 weeks of treatment in the OLE, each participant completed a DBPCFC consisting of placebo and each of their three specific foods to a cumulative dose of 8044 mg protein of each food.

Objectives

[0102] *Primary objective:* To compare the ability to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab.

[0103] *Secondary objective:* To evaluate safety during treatment with either omalizumab or placebo for omalizumab.

[0104] *Exploratory objectives:* To compare quality of life after treatment with either omalizumab or placebo for omalizumab. For the open label extension (OLE), to assess of the safety and efficacy of either 24 weeks (participants who received placebo prior to OLE) or 40 weeks (participants who received omalizumab prior to OLE) of treatment with omalizumab, and to assess quality of life at the end of either 24 or 40 weeks of treatment with omalizumab.

[0105] *Pharmacokinetic objectives:* To evaluate serum omalizumab concentrations during treatment with omalizumab. For the OLE, to assess serum omalizumab concentrations at the end of either 24 weeks (participants who received placebo prior to OLE) or 40 weeks (participants who received omalizumab prior to OLE) of treatment with omalizumab.

[0106] *Biomarker objectives:* To compare immunological responses after treatment with either omalizumab or placebo for omalizumab, and to determine whether immunological responses can be used to predict the ability to consume foods without dose-limiting systems during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. For the OLE, to assess immunological responses at the end of either 24 or 40 weeks of treatment with omalizumab.

Endpoints

[0107] *Primary endpoint:* Consumption of a single dose of ≥ 600 mg of peanut protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1. A participant who met this endpoint would be considered a “success” while a participant who did not meet this endpoint would be considered a “failure”.

[0108] *Key Secondary endpoints:* Consumption of a single dose of ≥ 1000 mg of cashew protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1;

consumption of a single dose of ≥ 1000 mg of milk protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1; and consumption of a single dose of ≥ 1000 mg of egg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1.

[0109] *Other secondary endpoints:* Consumption of a single dose of ≥ 600 mg, ≥ 1000 mg, ≥ 1 dose of 2000 mg, or 2 doses of 2000 mg protein of each food, at least two foods, or all three foods without dose-limiting symptoms during the DBPCFC at the end of Stage 1 (except for those endpoints already defined by the primary and key secondary endpoints in Stage 1); and number of foods consumed at a single dose of ≥ 600 mg, ≥ 1000 mg, ≥ 1 dose of 2000 mg, or 2 doses of 2000 mg protein of each food without dose-limiting symptoms during the DBPCFC at the end of Stage 1.

[0110] *Safety endpoints:* an adverse event related to study therapy regimen received during Stage 1 or received during Stage 1 OLE.

[0111] *Exploratory endpoints:* Percent change in the maximum dose of food protein consumed without dose-limiting symptoms during the DBPCFC at the end of Stage 1; consumption of a single dose of ≥ 600 mg, ≥ 1000 mg, ≥ 1 dose of 2000 mg, ≥ 2 doses of 2000 mg, or 3 doses of 2000 mg protein of each food, at least two foods, or all three foods without dose-limiting symptoms during the DBPCFC at the end of Stage 1 OLE; number of foods consumed at a single dose of ≥ 600 mg, ≥ 1000 mg, ≥ 1 dose of 2000 mg, ≥ 2 doses of 2000 mg, or 3 doses of 2000 mg protein of each food without dose-limiting symptoms during the DBPCFC at the end of Stage 1 OLE; and change in quality of life (QoL). QoL was assessed between Week 0 in Stage 1, at the first DBPCFC visit at the end of Stage 1, and for those participants who move to Stage 1 OLE, between Week 0 in Stage 1 and the first omalizumab injection visit in Stage 1 OLE, the first DBPCFC visit at the end of Stage 1 OLE, and the last DBPCFC visit at the end of Stage 1 OLE.

[0112] QoL was measured by the Food Allergy Quality of Life Questionnaire – Parent Form (FAQLQ-PF) for participants aged 0-12 years; Food Allergy Quality of Life Questionnaire – Child Form (FAQLQ-CF) for children/adolescents aged 8-12 years; Food Allergy Quality of Life Questionnaire – Teenager Form (FAQLQ-TF) for participants aged 13-17 years; and Food Allergy Quality of Life Questionnaire – Adult Form (FAQLQ-AF) (Flokstra-de Blok, B.M.J. (2014). Food Allergy Quality of Life Questionnaires (FAQLQ). In: Michalos, A.C. (eds) Encyclopedia of Quality of Life and Well-Being Research. Springer, Dordrecht) for participants aged 18 years and older.

[0113] *Pharmacokinetic exploratory endpoints:* Omalizumab trough concentration at the first Screening DBPCFC visit, the first DBPCFC visit at the end of Stage 1, and the first DBPCFC visit at the end of Stage 1 OLE for those participants who moved to Stage 1 OLE.

[0114] *Biomarker exploratory endpoints:* Total immunoglobulin E (IgE), total free IgE, allergen-specific IgE, allergen-specific immunoglobulin G4 (IgG4), allergen-specific immunoglobulin A (IgA), IgG4/IgE ratio, basophil activation, and skin prick tests (SPTs). Allergen-specific immune biomarkers (allergen-specific IgE, allergen-specific IgG4, allergen-specific IgA, basophil activation, and SPTs) were evaluated using peanut and the two other participant-specific foods. Immune biomarkers were analyzed at the following times: first Screening DBPCFC visit; first DBPCFC visit at the end of Stage 1; and first DBPCFC visit at the end of Stage 1 OLE (for those participants who move to Stage 1 OLE). Mechanistic exploratory endpoints, including dendritic cell and T cell assays, were measured at the following times: first Screening DBPCFC visit and first DBPCFC visit at the end of Stage 1.

[0115] ImmunoCAP™ Total IgE marketed by ThermoFisher Scientific was used to measure circulating IgE in serum and plasma (EDTA and heparin) samples according to the manufacturer's instructions, from participants prior to initiation of therapy with omalizumab or placebo. ImmunoCAP™ Total IgE is a quantitative enzyme linked immunosorbent assay, which measures circulating IgE within a range of 2 to 5000 kU/L (2 to 5000 IU/mL or about 2.4 ng/mL). A person having ordinary skill in the art can develop or use alternative assays, including ELISAs, to measure levels of human IgE in the serum or plasma of a subject.

Treatments

[0116] *Omalizumab:* Omalizumab is a recombinant humanized immunoglobulin G1 monoclonal antibody that binds to the FcεR1 binding epitope of human IgE, preventing human IgE from binding to its specific high-affinity receptors on mast cells and basophils. Omalizumab is approved by the European Commission and US FDA for patients with moderate-severe asthma ≥6 years of age and for patients with chronic idiopathic urticaria ≥12 years of age. Omalizumab is not currently approved for treating food allergy in patients of any age.

[0117] *Placebo for omalizumab:* The composition of the placebo for omalizumab was the same as the composition of the active study drug without the omalizumab.

[0118] Omalizumab and placebo for omalizumab were administered as a subcutaneous injection according to the omalizumab dosing table of **FIG. 2**. Throughout Stage 1 and Stage 1 OLE, each participant and/or their parent/guardian were instructed to strictly avoid all foods to which they are allergic.

Patient Selection Criteria

[0119] Patient Selection Inclusion Criteria

- 1 year to less than 56 years of age at Screening.
- Peanut allergy and:
 1. Positive SPT (≥ 4 mm wheal greater than saline control) to peanut;
 2. Positive peanut IgE (≥ 6 kUA/L) at Screening or within three months of Screening, determined by ImmunoCapTM; and
 3. Positive blinded oral food challenge (OFC) to peanut during the Screening DBPCFC, defined as experiencing dose-limiting symptoms (see Table 1-1) at a single dose of ≤ 100 mg of peanut protein.
- Allergic to at least two of six other foods (*i.e.*, milk, egg, wheat, cashew, hazelnut, walnut; milk and egg allergy was defined as unable to tolerate both cooked and uncooked forms) and:
 1. Milk, egg, or wheat:
 - Positive SPT (≥ 4 mm wheal greater than saline control) to food;
 - Positive food specific IgE (≥ 6 kUA/L) at Screening or within three months of Screening, determined by ImmunoCapTM; and
 - Positive blinded OFC to food during the Screening DBPCFC, defined as experiencing dose-limiting symptoms (see Table 1-1) at a single dose of ≤ 300 mg of food protein.
 2. Cashew, hazelnut, or walnut:
 - Positive SPT (≥ 4 mm wheal greater than saline control) to food or positive food specific IgE (≥ 6 kUA/L) at Screening or within three months of Screening, determined by ImmunoCapTM; and
 - Positive blinded OFC to food during the Screening DBPCFC, defined as experiencing dose-limiting symptoms (see Table 1-1) at a single dose of ≤ 300 mg of food protein.
- Body weight (as measured at Screening) and total serum IgE level (as measured within three months of Screening) suitable for omalizumab dosing.

- Was willing to be trained and provide an epinephrine autoinjector for the duration of the study.

[0120] Patient Selection Exclusion Criteria

- Clinically significant laboratory abnormalities at screening
- Dose-limiting symptoms to the blinded OFC to placebo during Screening DBPCFC.
- Sensitivity or suspected or known allergy to any ingredients or excipients of the active or placebo OFC material, or drugs related to omalizumab.
- Poorly controlled atopic dermatitis at screening.
- Poorly controlled or severe asthma or wheezing at screening, such as at least one of:
 1. Global Initiative for Asthma criteria regarding asthma control latest guidelines;
 2. History of two or more systemic corticosteroid courses within six months of screening or one course of systemic corticosteroids within three months of screening to treat asthma or wheezing;
 3. Prior intubation or mechanical ventilation for asthma or wheezing,
 4. One hospitalization or emergency department visit for asthma or wheezing within six months of screening;
 5. Forced expiratory volume in one second (FEV1) <80% of predicted or FEV1/forced vital capacity (FVC) <75%, with or without controller medications (only for participants who are aged seven years or older and are able to perform spirometry); and/or
 6. Inhaled corticosteroid (ICS) dosing of >500 mcg daily fluticasone.
- History of severe anaphylaxis to participant-specific foods.
- Treatment with a burst of oral, intramuscular, or intravenous steroids of more than two days for an indication other than asthma or wheezing within 30 days of screening.
- Currently receiving oral, IM, or IV corticosteroids, tricyclic antidepressants, or oral or topical β -blockers.
- History of eosinophilic gastrointestinal disease within three years of screening.
- History of cancer.
- Previous adverse reaction to omalizumab.
- History of any immunotherapy to any of the foods included in this study within six months of screening.

- Treatment with monoclonal antibody therapy, or other immunomodulatory therapy within six months of screening.
- In “build-up” phase of inhalant allergen immunotherapy.
- Inability to discontinue antihistamines for the minimum washout-periods for SPTs or OFCs.
- Participation in another therapeutic or interventional clinical study within 90 days of screening.
- Use of investigational drugs within 24 weeks of screening.
- Past or current medical problems, history of other chronic diseases requiring therapy, findings from physical assessment, or abnormalities in clinical laboratory testing, which may pose additional risks, interfere with participation, or impact quality or interpretation of data.

Screening

[0121] Participants who met initial eligibility criteria underwent a double-blinded, placebo-controlled, food challenge (DBPCFC) according to the dosing schedule of **Table 1-2**. The DBPCFC consisted of four blinded oral food challenges (OFCs): three active OFCs (peanut and two additional foods) and one placebo OFC (oat). The DBPCFC was conducted in up to four separate visits. The food challenges were prepared from allergen food protein flours (active) and oat flour (placebo), respectively.

[0122] Food challenges were performed under medical supervision with emergency medications immediately available. The maximum cumulative dose for each blinded OFC during the Screening DBPCFC was 444 mg of protein. For the blinded OFC to peanut during the Screening DBPCFC, the maximum single dose given was 100 mg of peanut protein with the final single 300 mg dose consisting of placebo. For the additional blinded OFCs to two foods and the blinded OFC to placebo during the Screening DBPCFC, the maximum single dose given was 300 mg of the respective food protein/placebo.

[0123] After completing the Screening DBPCFC, participants who experienced dose-limiting symptoms to a single dose of ≤ 100 mg of peanut protein, ≤ 300 mg protein for each of the other two foods, and no dose-limiting symptoms during the blinded OFC to placebo moved to Stage 1.

Table 1-2. Dosing Schedule for DBPCFC Screening

Dose #	Food Protein/Placebo (mg protein)	Cumulative Dose (mg protein)
1	1	1
2	3	4
3	10	14
4	30	44
5	100	144
6 ¹	300	444

¹. During the blinded OFC to peanut, the 300 mg dose will be placebo so as not to surpass a maximum dose of 100 mg of peanut protein during the Screening DBPCFC and to preserve blinding.

Stage 1

[0124] Stage 1 assessed whether 16-20 weeks of treatment with omalizumab versus placebo for omalizumab would increase the proportion of participants who consumed each of the foods under study without dose-limiting symptoms, as assessed by a DBPCFC. Participants who experienced dose-limiting symptoms to a single dose of ≤ 100 mg of peanut protein, ≤ 300 mg protein for each of the other two foods, and no dose-limiting symptoms to placebo at any single dose up to 300 mg protein during the Screening DBPCFC were randomized 2:1 to 16-20 weeks of treatment with omalizumab or placebo for omalizumab per the dosing table provided in **FIG. 2**. This dosing table was specifically designed to accommodate the food allergy patient population characteristics (*i.e.*, lower body weight and/or higher baseline total serum IgE level) of the OUtMATCH clinical trial.

[0125] During Stage 1, each participant (and/or a parent or guardian) was instructed to strictly avoid all foods to which they were allergic. Each randomized participant visited the clinic every two or four weeks, depending on assigned dosing frequency, for subcutaneous injection of omalizumab or placebo for omalizumab. Each participant was observed for at least two hours after the first three injections and for at least 30 minutes after all subsequent injections to assess for the development of adverse events (AEs).

[0126] After 16 weeks of treatment, each participant was subjected to a DBPCFC according to the dosing schedule of **Table 1-3**, consisting of placebo and each of their three specific foods to a cumulative dose of 6044 mg protein of each food. The DBPCFC took place within a maximum period of 28 days from the last treatment. Each participant who did not complete Stage 1 (*i.e.*, does not complete all four blinded OFCs comprising the DBPCFC at the end of Stage 1) was withdrawn from the study and asked to attend an Early

Discontinuation Visit. The first 60 participants who completed Stage 1 participated in the Stage 1 OLE.

Table 1-3. Dosing Schedule for a DBPCFC at the End of Stage 1 and Stage 1 OLE

Dose #	Food Protein/Placebo (mg protein)	Cumulative Dose (mg protein)
1	1	1
2	3	4
3	10	14
4	30	44
5	100	144
6	300	444
7	600	1044
8	1000	2044
9	2000	4044
10	2000	6044
11 ¹	2000	8044

¹. Dose 11 was only performed for the DBPCFC at the end of Stage 1 OLE.

Stage 1 OLE

[0127] Each participant received 24-28 weeks of open label omalizumab, before being subjected to a DBPCFC according to the dosing schedule of **Table 1-3**, consisting of placebo or each of their three specific foods to a cumulative dose of 8044 mg protein of each food. The DBPCFC took place within a maximum period of 28 days from the last treatment. Each participant who did not complete Stage 1 OLE (i.e., does not complete all four blinded OFCs comprising the DBPCFC at the end of OLE) was withdrawn from the study and asked to attend an Early Discontinuation Visit.

Interim Results

[0128] A preplanned interim analysis (IA) for efficacy was performed based on pre-specified thresholds for the primary and key secondary endpoints (p-value less than 0.0001 for peanut and less than 0.005 for each of cashew, milk and egg) that were agreed to by the United States Food and Drug Administration (USFDA). The interim analysis was conducted after the first 165 pediatric participants (ages 1 year to less than 18 years) either completed or discontinued Stage 1. A total of 92 pediatric males and 73 pediatric females (of which, 61 patients were aged 1 to less than 6 years of age and 104 patients aged 6 to less than 18 years) and 3 adult patients were included in the analysis. Patient weight ranged from approximately 10.1 kg to approximately 86.3 kg, with a mean and a median weight of approximately 30.7 kg and 25.5 kg, respectively.

[0129] Stage 1 of the study met pre-defined thresholds for significance for both primary and key secondary endpoints. The interim results were reviewed by the Data Safety Monitoring Board, who recommended stopping Stage 1 with no further enrollment due to efficacy of omalizumab monotherapy. At the time the study was halted, 180 participants were enrolled, including 177 pediatric participants and 3 adult participants. Topline clinical study results from the interim analysis provide strong evidence that omalizumab reduces the risk of having an allergic reaction as a consequence of oral exposure to food allergens.

[0130] Both primary and key secondary endpoints (single dose of ≥ 600 mg of peanut and ≥ 1000 mg of cashew, milk, or egg protein, respectively) achieved pre-defined statistical significance based on the proportion of participants without dose-limiting symptoms during the Double-Blind Placebo-Controlled Food Challenge (DBPCFC) at the end of Stage 1. The safety profile between omalizumab-treated and placebo-treated participants was generally comparable.

[0131] Baseline demographics were generally balanced across treatment arms. The mean age across treatment arms was 7.8 years for the pediatric participants: 37% were <6 years of age, 37.6% were age 6 to <12 years, and 25.5% were age 12 to <18 years. Among the pediatric participants, 92 males (55.8%) and 73 females (44.2%) were enrolled. For the adult participants, 3 males with ages 18, 20, and 28 years were enrolled. Ninety seven percent of participants completed Stage 1.

Efficacy

[0132] At the Screening DBPCFC, all 165 participants had dose-limiting reaction to ≤ 100 mg of peanut protein, 94 participants had dose-limiting reaction to ≤ 100 mg of cashew, 67 participants had dose-limiting reaction to ≤ 100 mg of milk, and 55 participants had dose-limiting reaction to ≤ 100 mg of egg.

[0133] The study met the primary endpoint and achieved statistical significance on the proportion of participants who could consume a single dose of ≥ 600 mg of peanut protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1. In the omalizumab-treated group, 68.2% of participants passed the DBPCFC compared to 5.5% in placebo (Δ : 62.7%, OR: 37.14, $p < 0.00001$).

[0134] The study also met all the key secondary endpoints. For cashew, 42.2% in the omalizumab-treated group versus 3.3% in placebo passed the DBPCFC (Δ : 38.9%, OR: 21.16, $p=0.00006$), for milk 65.8% versus 10.5% passed (Δ : 55.3%, OR: 16.35, $p=0.00008$), and for egg 67.4% versus 0 passed (Δ : 67.4%, OR: Infinity, $p < 0.00001$).

Table 1-4. Key Results from Interim Analysis

	Peanut (600mg) (N=165)	Cashew (1000mg) (N=94)	Milk (1000mg) (N=57)	Egg (1000mg) (N=65)
Omalizumab, n	110	64	38	46
Success n (%)	75 (68.2%)	27 (42.2%)	25 (65.8%)	31 (67.4%)
Failure n (%)	35 (31.8%)	37 (57.8%)	13 (34.2%)	15 (32.6%)
Placebo, n	55	30	19	19
Success n (%)	3 (5.5%)	1 (3.3%)	2 (10.5%)	0 (0%)
Failure n (%)	52 (94.5%)	29 (96.7%)	17 (89.5%)	19 (100%)
Difference Omalizumab - Placebo (95% CI)	0.627 (0.4956, 0.7260)	0.389 (0.1993, 0.5281)	0.553 (0.2886, 0.7310)	0.674 (0.4880, 0.8047)
Odds Ratio (OR) Omalizumab/ Placebo 95% CI	37.143 (10.6286, 194.0379)	21.162 (3.0326, 895.6612)	16.346 (2.9818, 158.7890)	Infinity (10.1446, Infinity)
P-Value*	<0.00001	0.00006	0.00008	<0.00001

*2-sided p-value from Fisher's exact test.

[0135] Key results are listed in **Table 1-4**. Data from the OLE further support that omalizumab treatment is associated with a higher probability of passing the DBPCFC at the end of treatment and that the response from omalizumab administration is durable. For

peanut, 72.1% of participants had no dose-limiting symptoms with ≥ 600 mg of peanut protein at the end of the Stage 1 OLE. Among participants with allergy to the foods tested as key secondary endpoints, 55.6% had no dose-limiting symptoms with ≥ 1000 mg of cashew, 76.0% of participants had no dose-limiting symptoms with ≥ 1000 mg of milk, and 77.8% had no dose-limiting symptoms with ≥ 1000 mg of egg. Response rates were higher among participants who received omalizumab compared to participants who received placebo for omalizumab in the placebo-controlled part of Stage 1.

[0136] Results also showed efficacy in the ability of treated subjects to consume doses of multiple foods without experiencing dose-limiting symptoms. Participants in the omalizumab and placebo groups were compared for their ability to consume a single dose of ≥ 600 mg, a single dose ≥ 1000 mg, ≥ 1 dose of 2000 mg, or 2 doses of 2000 mg of at least 2 of their participant-specific tested foods without dose-limiting symptoms during the DBPCFC at the end of Stage 1. Minimal numbers (1 to 3) participants treated with placebo were able to achieve these endpoints compared to many in the omalizumab group; for example, 47/110 placebo participants were able to consume 2 doses of 2000 mg of at least 2 of the tested foods compared to 1/55 in the placebo group ($\Delta = 0.409$, 95% CI: 0.2980298, 0.5100510; $p < 0.00001$).

[0137] Participants in the omalizumab and placebo for omalizumab groups were compared for their ability to consume a single dose of ≥ 600 mg, a single dose of ≥ 1000 mg, ≥ 1 dose of 2000 mg, or 2 doses of 2000 mg of all 3 foods tested without dose-limiting symptoms during the DBPCFC at the end of Stage 1. One participant treated with placebo was able to consume a single dose of ≥ 600 mg of all 3 foods compared to almost half (53/110) participants in the omalizumab group ($\Delta = 0.445$, 95% CI: 0.3197320, 0.5491549; $p < 0.00001$). No participants treated with placebo were able to consume 2 doses of 2000 mg of all 3 foods tested without dose-limiting symptoms compared to 27/110 participants in the omalizumab group ($\Delta = 0.245$, 95% CI: 0.1614, 0.3367; $p < 0.00001$).

[0138] Odds ratios were calculated comparing the consumption of a higher number of foods without dose-limiting symptoms during the DBPCFCs at the end of Stage 1 between participants in the omalizumab and placebo for omalizumab groups. Whether challenges were with a single dose of ≥ 600 mg of each food, ≥ 1000 mg of each food, ≥ 1 dose of 2000 mg of each food, or 2 doses of 2000 mg of each food, participants in the omalizumab group were able to consume more foods than participants in the placebo group. For challenges with single doses of ≥ 600 mg of each food, 48.2% (53/110) of participants were able to consume 3

foods without dose-limiting symptoms, whereas only 3.6% (2/55) of participants in the placebo group were able to do so; 89.1% (49/55) participants in the placebo group were not able to consume any foods at this dose without dose-limiting symptoms. The odds ratio comparing the omalizumab and placebo for omalizumab groups was 37.791 (95% CI: 14.2527253, 100.2025203; $p < 0.00001$). Similar results were observed for all dose levels of food challenges.

[0139] In this study in patients with food allergy, omalizumab treatment led to a reduction in serum free IgE and an increase in serum total IgE levels, similar to observations of asthma patients treated with omalizumab. The mean total IgE concentration at baseline was 810 IU/mL. After repeated dosing every 2 or 4 weeks, with dosage and frequency according to the dosing table in **FIG. 2**, the mean pre-dose free IgE concentration at Week 16 was 10.0 IU/mL, representing an approximately 99% reduction. **Table 1-5** below shows free IgE levels. Total IgE levels in serum increased about 2.4-fold due to the formation of omalizumab-IgE complexes, which have a longer half-life compared with free IgE.

Table 1-5. Total Serum IgE Levels

Statistic	Omalizumab (N=110)	Placebo (N=55)	Overall (N=165)
Screening			
N	37	18	55
Mean	1960.1	1932.9	1951.2
SD	1402.0	1050.2	1287.5
Median	1548.8	1629.9	1548.8
Minimum	418.7	580.9	418.7
Maximum	6935.7	4128.5	6935.7
After Stage 1			
N	39	19	58
Mean	20.0	2324.7	775.0
SD	9.8	1242.7	1295.5
Median	20.4	2093.3	24.9
Minimum	5.2	479.2	5.2
Maximum	48.6	4888.4	4888.4
% Change from Screening to Stage 1			
N	35	18	53
Mean	-98.6	42.2	-50.8
SD*	1.1	63.7	76.5
Median	-98.8	28.5	-98.3
Minimum	-99.7	-35.1	-99.7
Maximum	-95.1	202.3	202.29

*SD = standard deviation

Safety

[0140] The safety profile between omalizumab-treated and placebo-treated participants was generally comparable. The proportion of patients reporting an adverse event (AE) was numerically higher in the placebo arm. The majority of AEs were non serious and Grade 1 or 2 in severity. The number of participants with AEs of special interest and serious AEs (SAEs) was low. There were no deaths in the study.

[0141] Further, there were no AEs related to the key risks for omalizumab treatment such as anaphylaxis, arterial thrombotic events, or malignancies. The observed AEs were consistent with the known safety profile of omalizumab treatment, and no adverse drug reactions were identified from the initial review of the safety data.

Stage 1 Adverse Events (AE)

[0142] In Stage 1, a majority of the participants (112 participants, 67.9%) experienced at least one treatment-emergent AE (TEAE) for a total of 346 TEAEs. In the omalizumab group, 69 (62.7%) participants experienced a combined total of 216 TEAEs. In the placebo group, 43 (78.2%) participants experienced 130 TEAEs.

[0143] The most common system organ classes (SOCs) in which TEAEs were experienced by $\geq 15\%$ of the participants were: Infections and Infestations (45 participants, 27.3%); Immune System Disorders (42 participants, 25.5%); General disorders and administration site conditions (34 participants, 20.6%); and Respiratory, thoracic, and mediastinal disorders (27 participants, 16.4%).

[0144] The most frequently reported TEAEs with an incidence $\geq 3\%$ of the participants in Stage 1 were: hypersensitivity (35 participants, 21.2%); injection site reaction (16 participants, 9.7%); coronavirus infection (11 participants, 6.7%); pyrexia (9 participants, 5.5%); upper respiratory tract infection (8 participants, 4.8%); viral infection, asthma, urticaria, and diarrhea (7 participants, 4.2%); vomiting and cough (6 participants, 3.6%); and gastroenteritis and atopic dermatitis (5 participants, 3.0%).

[0145] Twenty-four participants (21.9 %) experienced a total of 43 AEs related to omalizumab treatment. Among these AEs, injection site reaction was the most commonly reported related AE (11 participants reported 20 AEs).

[0146] Four (2.4 %) participants experienced a total of 4 SAEs. In the omalizumab group, 3 (2.7%) participants experienced 3 SAEs (liver function test increased, systemic inflammatory response syndrome, and infectious mononucleosis). In the placebo group, one (1.8%) participant experienced 1 SAE (hypersensitivity).

[0147] A majority of the participants experienced AEs of Grade 1-2 in severity (97 participants, 58.8 %). Grade 3-4 severity AEs were experienced by 15 participants. Twelve participants (7.3 %) experienced Grade 3 AEs and 3 participants (1.8 %) experienced Grade 4 AEs. No grade 5 AEs were reported. One participant in the omalizumab group experienced one AE that led to treatment withdrawal. One participant in the omalizumab group experienced one AE of special interest (infectious mononucleosis).

Stage 1 OLE AEs

[0148] In the OLE, 42 (71.2 %) participants experienced 126 TEAEs.

[0149] The most common SOC in which TEAEs were experienced by $\geq 15\%$ of the participants were: Infections and Infestations (17 participants, 28.8%); General disorders and administration site conditions (12 participants, 20.3%); Immune System Disorders (12 participants, 20.3%); and Respiratory, thoracic, and mediastinal disorders (9 participants, 15.3%)

[0150] The most frequently reported TEAEs experienced by ≥ 5 participants in the Stage 1 OLE were: hypersensitivity (9 participants, 15.3%) and injection site reaction (8 participants, 13.6%).

[0151] Sixteen participants (27.1 %) experienced a total of 28 AEs related to omalizumab. Among these AEs, injection site reaction was the most commonly reported related AE (8 participants reported 12 AEs).

[0152] A majority of the participants experienced AEs of Grade 1-2 severity (40 participants, 67.8 %). Grade 3 severity AEs were experienced by 2 participants (3.4%). No grade 4 or 5 AEs were reported. No SAEs, AEs leading to treatment withdrawal, or AE of special interest were reported.

Pharmacodynamics

[0153] Observed post-treatment free IgE generally fell within the target range, with a mean ($\pm$ SD) of 24.5 ($\pm$ 11.9) ng/mL at Week 16 (Stage 1).

[0154] The present disclosure is described in detail in the above example(s), which are offered to illustrate the disclosure. The example(s) are not in any way intended to limit the scope of the disclosure unless otherwise indicated in the claims. The attached figures are meant to be considered as integral parts of the specification.

SEQUENCES

SEQ ID NO:1

>Omalizumab-Heavy

```

1 EVQLVESGGG LVQPGGSLRL SCAVSGYSIT SGYSWNWIRQ APGKGLEWVA
51 SITYDGSTNY NPSVKGRITI SRDDSKNTFY LQMNSLRAED TAVYYCARGS
101 HYFGHWHFAV WGQGTTLVTVS SASTKGPSVF PLAPSSKSTS GGTAALGCLV
151 KDYFPEPVTV SWNSGALTSG VHTFPAVLQS SGLYSLSSVV TVPSSSLGTQ
201 TYICNVNHKP SNTKVDKKVE PKSCDKHTC PPCPAPELLG GPSVFLFPPK
251 PKDTLMISRT PEVTCVVVDV SHEDPEVKFN WYVDGVEVHN AKTKPREEQY
301 NSTYRVVSVL TVLHQDWLNG KEYKCKVSNK ALPAPIEKTI SKAKGQPREP
351 QVYTLPPSRE EMTKNQVSLT CLVKGFYPSD IAVEWESNGQ PENNYKTTPP
401 VLDSGGSFFL YSKLTVDKSR WQQGNVFSCS VMHEALHNHY TQKSLSLSPG
451 X

```

wherein X can be lysine (K) or absent

SEQ ID NO:2

>Omalizumab-Light

```

1 DIQLTQSPSS LSASVGDRVIT ITCRASQSDV YDGDSYMNWY QQKPGKAPKL
51 LIYAASYLES GVPSRFSGSG SGTDFTLTIS SLQPEDFATY YCQQSHEDPY
101 TFGQGTKVEI KRTVAAPSVF IFPPSDEQLK SGTASVVCLL NNFYPREAKV
151 QWKVDNALQS GNSQESVTEQ DSKDSTYSLT STLTLISKADY EKHKVYACEV
201 THQGLSSPVT KSFNRGEC

```

SEQ ID NO:3

>Omalizumab-VH

```

1 EVQLVESGGG LVQPGGSLRL SCAVSGYSIT SGYSWNWIRQ APGKGLEWVA
51 SITYDGSTNY NPSVKGRITI SRDDSKNTFY LQMNSLRAED TAVYYCARGS
101 HYFGHWHFAV WGQG

```

SEQ ID NO:4

>Omalizumab-VL

```

1 DIQLTQSPSS LSASVGDRVIT ITCRASQSDV YDGDSYMNWY QQKPGKAPKL
51 LIYAASYLES GVPSRFSGSG SGTDFTLTIS SLQPEDFATY YCQQSHEDPY
101 TFGQGTKVEI KRTV

```

SEQ ID NO:5

>CDR-H1

GYSITSGY

SEQ ID NO:6

>CDR-H2

TYDGS

SEQ ID NO:7

>CDR-H3

GSHYFGHWHFAV

SEQ ID NO:8

>CDR-L1

RASQSVDDYDGDSYMN

SEQ ID NO:9

>CDR-L2

AASYLES

SEQ ID NO:10

>CDR-L3

QQSHEDPYT

CLAIMS

We claim:

1. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection to the subject once about every two weeks a pharmaceutical composition comprising omalizumab at a dose of from 150 mg to 300 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml.

2. The method of claim 1, wherein the dose of omalizumab administered about every two weeks is:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml; or

150 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

150 mg when the body weight of the subject is greater than 15 kg and less than or equal to 20 kg and the total serum IgE level of the subject is greater than 700 IU/ml and less than or equal to 900 IU/ml.

3. The method of claim 1, wherein the dose of omalizumab administered about every two weeks is:

225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 2000 IU/ml; or

225 mg when the body weight of the subject is greater than 15 kg and less than or equal to 20 kg and the total serum IgE level of the subject is greater than 900 IU/ml and less than or equal to 1300 IU/ml.

4. The method of claim 1, wherein the dose of omalizumab administered about every two weeks is:

300 mg when the body weight of the subject is greater than 15 kg and less than or equal to

20 kg and the total serum IgE level of the subject is greater than 1300 IU/ml and less than or equal to 2000 IU/ml.

5. The method of any one of claims 1-4, wherein the subject is from 1 year to 5 years of age.

6. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection to the subject once about every two weeks a pharmaceutical composition comprising omalizumab at a dose of from 375 mg to 450 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is greater than 20 kg and less than or equal to 30 kg and total serum IgE level of the subject is greater than 1,500 IU/ml and less than or equal to 2,000 IU/ml.

7. The method of claim 6, wherein the body weight of the subject is greater than 20 kg and less than or equal to 25 kg.

8. The method of claim 7, wherein the dose of omalizumab administered about every two weeks is 375 mg.

9. The method of claim 6, wherein the body weight of the subject is greater than 25 kg and less than or equal to 30 kg.

10. The method of claim 9, wherein the dose of omalizumab administered about every two weeks is 450 mg.

11. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection to the subject once about every two weeks a pharmaceutical composition comprising omalizumab at a dose of from 150 mg to 225 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml.

12. The method of claim 11, wherein the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg.

13. The method of claim 12, wherein the dose of omalizumab administered about every two weeks is 150 mg.
14. The method of claim 13, wherein the total serum IgE level of the subject is greater than 700 IU/ml and less than or equal to 1,500 IU/ml.
15. The method of claim 11, wherein the body weight of the subject is greater than 12 kg and less than or equal to 15 kg.
16. The method of claim 15, wherein the dose of omalizumab administered about every two weeks is 150 mg when the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1,200 IU/ml.
17. The method of claim 16, wherein the total serum IgE level of the subject is greater than 700 IU/ml and less than or equal to 1,200 IU/ml.
18. The method of claim 15, wherein the dose of omalizumab administered about every two weeks is 225 mg when the total serum IgE level of the subject is greater than 1,200 IU/ml and less than or equal to 2,000 IU/ml.
19. The method of any one of claims 11-18, wherein the subject is from 1 year to 5 years of age.
20. The method of claim 19, wherein the subject is from 1 year to 3 years of age.
21. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:
 - administering by subcutaneous injection to the subject once about every four weeks a pharmaceutical composition comprising omalizumab at a dose of from 75 mg to 150 mg,
 - wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 600 IU/ml.
22. The method of claim 21, wherein the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg.

23. The method of claim 22, wherein the dose of omalizumab administered once about every four weeks is 75 mg when the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml.
24. The method of claim 22, wherein the dose of omalizumab administered once about every four weeks is 150 mg when the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml.
25. The method of claim 21, wherein the body weight of the subject is greater than 12 kg and less than or equal to 15 kg.
26. The method of claim 25, wherein the dose of omalizumab administered once about every four weeks is 75 mg when the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml.
27. The method of claim 25, wherein the dose of omalizumab administered once every four weeks is 150 mg when the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml.
28. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:
administering by subcutaneous injection to the subject once about every two weeks a pharmaceutical composition comprising a therapeutically effective amount of omalizumab,
wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg.
29. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:
administering by subcutaneous injection to the subject once about every two to four weeks a pharmaceutical composition comprising a therapeutically effective amount of omalizumab,
wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 25 kg.
30. The method of claim 28 or claim 29, wherein the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg.

31. The method of claim 28 or claim 29, wherein the body weight of the subject is greater than 12 kg and less than or equal to 15 kg.
32. The method of claim 29, wherein the body weight of the subject is greater than 15 kg and less than or equal to 20 kg.
33. The method of claim 29, wherein the body weight of the subject is greater than 20 kg and less than or equal to 25 kg.
34. The method of claim 30 or claim 31, wherein total serum IgE level of the subject prior to administration of the first dose of omalizumab is greater than 600 IU/ml and less than or equal to 2,000 IU/ml.
35. The method of any one of claims 30-33, wherein the total serum IgE level of the subject prior to administration of the first dose of omalizumab is greater than 1,500 IU/ml and less than or equal to 1,850 IU/ml.
36. The method of any one of claims 1-35, wherein the subject has not been diagnosed with allergic rhinoconjunctivitis prior to administration of the first dose of omalizumab.
37. The method of any one of claims 1-36, wherein the subject has not been diagnosed with asthma, nasal polyps, or chronic spontaneous urticaria prior to administration of the first dose of omalizumab.
38. The method of any one of claims 1-37, wherein the food allergy comprises allergy to one or more food allergens selected from the group consisting of peanut, milk, egg, wheat, cashew, hazelnut, or walnut, and a combination thereof.
39. The method of claim 38, wherein the food allergy comprises allergy to two or more allergens selected from the group consisting of peanut, milk, egg, wheat, cashew, hazelnut, or walnut, and a combination thereof.
40. The method of claim 38, wherein the food allergy comprises allergy to peanut and allergy to two or more allergens selected from milk, egg, wheat, cashew, hazelnut and walnut.
41. The method of claim 40, wherein the subject was identified as having food allergy to multiple food allergens prior to the administering step according to criteria comprising:

a) a skin-prick test resulting in a wheal of at least 4 mm in diameter to peanut and two or more of milk, egg, wheat, cashew, hazelnut and walnut; and/or

b) a peanut IgE level of at least 6 kUA/L and an IgE level of at least 6 kUA/L to two or more allergens selected from milk, egg, wheat, cashew, hazelnut and walnut; and/or

c) development of a moderate-to-severe allergic reaction after consumption of about 100 mg of peanut protein, and/or consumption of about 300 mg of milk, egg, wheat, cashew, hazelnut and/or walnut protein.

42. The method of any one of claims 1-40, wherein the allergic reaction is a moderate-to-severe allergic reaction.

43. The method of claim 42, wherein the moderate-to-severe allergic reaction to a food comprises onset of one or more symptoms after consumption of about 100 mg of peanut protein, and/or consumption of about 300 mg of milk, egg, wheat, cashew, hazelnut and/or walnut protein, and wherein the one or more symptoms comprise one or more:

skin: systemic hives, more than mild lip or face edema, pruritus causing protracted scratching, several areas of erythema pronounced erythema, and combinations thereof; and/or

respiratory: throat tightness with or without hoarseness, persistent cough, wheezing with or without dyspnea, laryngeal edema, stridor, and combinations thereof; and/or

gastrointestinal tract: moderate to severe abdominal pain, cramping, nausea, vomiting, and combinations thereof; and/or

neurological: change in mental status; and/or

circulatory: hypotension.

44. The method of any one of claims 1-43, wherein preventing the allergic reaction permits the subject to consume a single dose of about 600 mg of peanut protein, and/or a single dose of about 1000 mg of milk, egg, wheat, cashew, hazelnut and/or walnut protein without triggering dose-limiting symptoms.

45. The method of any one of claims 1-43, wherein preventing the allergic reaction permits the subject to consume a single dose of about 1000 mg of peanut, milk, egg, wheat, cashew, hazelnut and/or walnut protein without triggering dose-limiting symptoms.

46. The method of any one of claims 1-43, wherein preventing the allergic reaction permits the subject to consume a single dose of about 2000 mg of peanut, milk, egg, wheat, cashew, hazelnut and/or walnut protein without triggering dose-limiting symptoms.

47. The method of any one of claims 1-43, wherein preventing the allergic reaction reduces likelihood that the subject will require treatment with antihistamine or epinephrine after consuming a single dose of about 100 mg of peanut protein, and/or a single dose of about 300 mg of milk, egg, wheat, cashew, hazelnut and/or walnut protein.

48. The method of any one of claims 1-47, further comprising determining the body weight and the total serum IgE level of the subject prior to administration of the first dose of omalizumab.

49. The method of claim 48, wherein determining the body weight and the total serum IgE level of the subject is done one within month prior to administration of the first dose of omalizumab.

50. The method of claim 49, wherein determining the body weight and the total serum IgE level of the subject is done two weeks prior to administration of the first dose of omalizumab.

51. The method of any one of claims 1-50, wherein duration of the administering step is at least 16 to 20 weeks in length.

52. The method of any one of claims 1-50, wherein duration of the administering step is at least 10 to 12 months in length.

53. The method of any one of claims 48-52, wherein determining the total serum IgE level is done with an enzyme-linked immunosorbent assay.

54. The method of any one of claims 1-53, wherein the pharmaceutical composition is an aqueous solution further comprising L-arginine hydrochloride, L-histidine, and L-histidine hydrochloride monohydrate.

55. The method of claim 54, wherein the pharmaceutical composition further comprises sucrose.

56. The method of any one of claims 1-55, wherein the method prevents or reduces allergic reaction in the subject following consumption of food containing the one or more food allergens.

57. The method of any one of claims 1-56, wherein the method does not comprise concurrent oral immunotherapy with the one or more food allergens.

58. A kit comprising:

- i) a pharmaceutical composition comprising omalizumab; and
- ii) instructions for administering the pharmaceutical composition according to the method of any one of claims 1-57.

59. The kit of claim 58, wherein the pharmaceutical composition is an aqueous solution present in a prefilled syringe.

60. The kit of claim 58, wherein the pharmaceutical composition is lyophilized powder present in a vial and the kit further comprises sterile water for injection and instructions for reconstitution of the powder with the sterile water.

61. The kit of claim 60, wherein the kit further comprises a syringe and a needle for subcutaneous injection of the pharmaceutical composition.

62. Omalizumab for use in a method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

- administering by subcutaneous injection once every two weeks to the subject a pharmaceutical composition comprising omalizumab at a dose of from 150 mg to 300 mg,
- wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml, and
- wherein the method does not comprise concurrent oral immunotherapy with the food allergen.

63. Omalizumab for use in a method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

- administering by subcutaneous injection once every two weeks to the subject a pharmaceutical composition comprising omalizumab at a dose of from 375 mg to 450 mg,
- wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 20 kg and less than or equal to 30 kg and total serum IgE level of the subject is greater than 1,500 IU/ml and less than or equal to 2,000 IU/ml, and

wherein the method does not comprise concurrent oral immunotherapy with the food allergen.

64. Omalizumab for use in a method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection once every two weeks to the subject a pharmaceutical composition comprising omalizumab at a dose of from 150 mg to 225 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml, and

wherein the method does not comprise concurrent oral immunotherapy with the food allergen.

65. Omalizumab for use in a method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:

administering by subcutaneous injection once every four weeks to the subject a pharmaceutical composition comprising omalizumab at a dose of from 75 mg to 150 mg,

wherein prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 600 IU/ml, and

wherein the method does not comprise concurrent oral immunotherapy with the food allergen.

66. Use of omalizumab at a dose of from 150 mg to 300 mg in the manufacture of a medicament for treating a human subject diagnosed with a food allergy to one or more food allergens, wherein the medicament is to be administered by subcutaneous injection once every two weeks to the subject when prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 20 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml, and wherein the medicament is not administered in combination with oral immunotherapy with the food allergen.

67. Use of omalizumab at a dose of from 375 mg to 450 mg in the manufacture of a medicament for treating a human subject diagnosed with a food allergy to one or more food

allergens, wherein the medicament is to be administered by subcutaneous injection once every two weeks to the subject when prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 20 kg and less than or equal to 30 kg and total serum IgE level of the subject is greater than 1,500 IU/ml and less than or equal to 2,000 IU/ml, and wherein the medicament is not administered in combination with oral immunotherapy with the food allergen.

68. Use of omalizumab at a dose of from 150 mg to 225 mg in the manufacture of a medicament for treating a human subject diagnosed with a food allergy to one or more food allergens, wherein the medicament is to be administered by subcutaneous injection once every two weeks to the subject when prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 2,000 IU/ml, and wherein the medicament is not administered in combination with oral immunotherapy with the food allergen.

69. Use of omalizumab at a dose of from 75 mg to 150 mg in the manufacture of a medicament for treating a human subject diagnosed with a food allergy to one or more food allergens, wherein the medicament is to be administered by subcutaneous injection once every four weeks to the subject when prior to administration of a first dose of omalizumab to the subject, body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 600 IU/ml, and wherein the medicament is not administered in combination with oral immunotherapy with the food allergen.

70. A method of treating a human subject diagnosed with a food allergy to one or more food allergens selected from the group consisting of peanut, cashew, milk and egg proteins, the method comprising administering to the human subject as effective amount of omalizumab by subcutaneous injection once every two or four weeks,

wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of at least about 3 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 600 mg of peanut protein, and/or a single dose of about 1000 mg of cashew protein, and/or a single dose of about 1000 mg milk protein, and/or a single dose of about 1000 mg egg protein,

optionally wherein the OR is from about 3 to about 900, or wherein the OR is from about 15 to about 45.

71. The method of claim 70, wherein the plurality of human subjects have a food allergy to peanut protein, and wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of from about 10 to about 200 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 600 mg of peanut protein, optionally wherein the OR is from about 30 to about 40, or wherein the OR is about 37.

72. The method of claim 70, wherein the plurality of human subjects have a food allergy to cashew protein, and wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of from about 3 to about 900 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 1000 mg of cashew protein, optionally wherein the OR is from about 15 to about 25, or wherein the OR is about 21.

73. The method of claim 70, wherein the plurality of human subjects have a food allergy to milk protein, and wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of from about 3 to about 160 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 1000 mg of milk protein, optionally wherein the OR is from about 10 to about 20, or wherein the OR is about 16.

74. The method of claim 70, wherein the plurality of human subjects have a food allergy to egg protein, and wherein administering omalizumab to a plurality of human subjects in the absence of oral immunotherapy results in an odds ratio (OR) of at least about 10 for preventing development of dose-limiting symptoms after the human subjects consume a single dose of about 1000 mg of egg protein, optionally wherein the OR is at least about 100, 1,000, 10,000, 100,000, or 1,000,000.

75. A method of treating a human subject diagnosed with a food allergy to one or more food allergens, the method comprising:
administering to the subject an anti-IgE antibody at a dose of from 75 mg to 300 mg,
wherein the subject has a body weight equal to or greater than about 10 kg and less than or

equal to about 20 kg, and the subject has a total serum IgE level equal to or greater than about 30 IU/ml.

76. The method of claim 75, wherein the anti-IgE antibody is omalizumab.

77. The method of claim 75, wherein the omalizumab is administered as a pharmaceutical composition comprising omalizumab.

78. The method of any one of claims 75 to 77, wherein the subject has a total serum IgE level equal to or greater than about 30 IU/ml and less than or equal to about 2,000 IU/ml.

79. The method of any one of claims 75 to 78, wherein each dose of anti-IgE antibody administered to the subject is determined prior to administration of the first dose of the anti-IgE antibody.

80. The method of any one of claims 75 to 79, wherein the subject has a total serum IgE level of equal to or greater than about 30 IU/ml and less than or equal to about 2,000 IU/ml prior to administration of the first dose of the anti-IgE antibody.

81. The method any one of claims 75 to 80, wherein the subject has a body weight equal to or greater than about 10 kg and less than or equal to about 20 kg prior to administration of the first dose of the anti-IgE antibody.

82. The method of any one of claims 75 to 81, wherein the dose of anti-IgE antibody is administered to the subject every two or four weeks.

83. The method of any one of claims 75 to 82, wherein the dose of anti-IgE antibody is

(i) 75 mg every 4 weeks if the subject has

a body weight of ≥ 10 -15 kg, and total serum IgE level of ≥ 30 -300 IU/ml, or

a body weight of ≥ 10 -20 kg, and total serum IgE level of ≥ 30 -200 IU/ml;

(ii) 150 mg every 4 weeks if the subject has

a body weight of ≥ 10 -15 kg, and total serum IgE level of > 300 -600 IU/ml,

a body weight of ≥ 10 -20 kg, and total serum IgE level of > 300 -400 IU/ml, or

a body weight of > 15 -20 kg, and total serum IgE level of > 200 -400 IU/ml;

(iii) 225 mg every 4 weeks if the subject has

a body weight of > 15 -20 kg, and total serum IgE level of > 400 -700 IU/ml;

(iv) 150 mg every 2 weeks if the subject has

a body weight of ≥ 10 -12 kg, and total serum IgE level of >600-1500 IU/ml,
a body weight of >12-15 kg, and total serum IgE level of >600-1200 IU/ml,
a body weight of ≥ 10 -15 kg, and total serum IgE level of >600-1200 IU/ml, or
a body weight of ≥ 10 -20 kg, and total serum IgE level of >700-900 IU/ml;

(v) 225 mg every 2 weeks if the subject has

a body weight of >12-15 kg, and total serum IgE level of >1200-1850 IU/ml, or
a body weight of >15-20 kg, and total serum IgE level of >900-1300 IU/ml; and

(vi) 300 mg every 2 weeks if the subject has

a body weight of >15-20 kg, and total serum IgE level of >1300-1850 IU/ml.

84. The method of any one of claims 75 to 83, wherein the dose of anti-IgE antibody is administered to the subject subcutaneously or intravenously.

85. The method of claim 84, wherein the dose of anti-IgE antibody is administered to the subject subcutaneously.

86. The method of claim 85, wherein the dose of anti-IgE antibody is administered to the subject by subcutaneous injection.

87. The method of any one of claims 75 to 86, wherein the dose of anti-IgE antibody is administered to the subject until said subject is no longer diagnosed with food allergy.

88. The method of any one of claims 75 to 87, wherein the subject is diagnosed with food allergy to more than one food allergen.

89. The method of any one of claims 75 to 88, wherein the food allergen comprises peanut protein.

90. The method of any one of claims 75 to 89, wherein the subject is greater than 1 year and less than 6 years of age.

91. The method of any one of claims 75 to 90, wherein the dose of anti-IgE antibody is not administered in combination with oral immunotherapy with the food allergen.

92. The method any one of claims 75 to 91, wherein the incidence of allergic reaction to the food allergen is reduced.

93. The method any one of claims 75 to 91, wherein the severity of allergic reaction to the food allergen is reduced.

94. The method any one of claims 75 to 91, wherein allergic reaction to the food allergen is prevented.

ABSTRACT

The present disclosure provides methods and kits for treating or preventing an allergic reaction to a food allergen consumed by a human subject with one or more food allergies. In particular, the present disclosure provides prophylactic therapies comprising administration of an anti-IgE antibody at a specific dose to a human subject who is allergic to one or more food allergens.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Ryan Patrick OWEN

Application No.: Not Yet Assigned

Confirmation No.: Not Yet Assigned

Filed: Concurrently Herewith

Art Unit: Not Yet Assigned

For: ANTI-IGE ANTIBODY THERAPY FOR
MULTIPLE FOOD ALLERGIES

Examiner: Not Yet Assigned

PRELIMINARY AMENDMENT UNDER 37 C.F.R. 1.115

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

INTRODUCTORY COMMENTS

Prior to examination on the merits, Applicant respectfully requests entry of this Preliminary Amendment for the above-captioned patent application.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims, which begins on page 3 of this paper.

Remarks/Arguments begin on page 9 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [0001] on page 1 with the following amended paragraph:

[0001] This application is a continuation of International Application No. PCT/US2023/070639, filed internationally on July 20, 2023, which claims priority to U.S. Provisional Application No. 63/512,051, filed July 5, 2023, the content of each of which is hereby incorporated by reference in its entirety.

Please replace paragraph [0002] on page 1 with the following amended paragraph:

[0002] The content of the electronic sequence listing (~~146392066840SEQLIST.xml; Size: 10,949 bytes; and Date of Creation: July 19, 2023~~) (146392066801seqlist.xml; Size: 10,952 bytes; and Date of Creation: September 15, 2023) is herein incorporated by reference in its entirety.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

1-94. (Canceled)

95. (New) A method of treating a human subject having an allergy to a food allergen, the method comprising:

administering to the subject by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab,

wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is from 150 mg to 225 mg, or the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is from 75 to 150 mg, and

wherein body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than or equal to 30 IU/ml and less than or equal to 1850 IU/ml.

96. (New) The method of claim 95, wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml;

150 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml.

97. (New) The method of claim 95, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:

75 mg when the body weight of the subject is equal to or greater than 10 kg and less than or

equal to 15 kg, and the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 300 IU/ml.

98. (New) The method of claim 95, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:

150 mg when the body weight of the subject is greater than or equal to 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml.

99. (New) The method of claim 95, wherein the pharmaceutical composition is administered to a subject having a body weight of greater than or equal to 10 kg and less than or equal to 12 kg at a dose of:

75 mg once about every four weeks if the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 300 IU/ml;

150 mg once about every four weeks if the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; and

150 mg once about every two weeks if the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml.

100. (New) The method of claim 95, wherein the pharmaceutical composition is administered to a subject having a body weight of greater than or equal to 12 kg and less than or equal to 15 kg at a dose of:

75 mg once about every four weeks if the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 300 IU/ml;

150 mg once about every four weeks if the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml;

150 mg once about every two weeks if the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; and

225 mg once about every two weeks if the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml.

101. (New) The method of claim 95, wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.

102. (New) The method of claim 95, wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

103. (New) The method of claim 95, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.

104. (New) The method of claim 95, wherein the method is not used for emergency treatment of at least one of an allergic reaction to the food allergen and anaphylaxis.

105. (New) The method of claim 95, wherein the subject is from 1 year to 5 years of age.

106. (New) The method of claim 95, wherein the food allergen comprises peanut.

107. (New) The method of claim 106, wherein the food allergen further comprises one or more of milk, egg, and cashew.

108. (New) The method of claim 95, wherein treating comprises reducing an allergic reaction following exposure of the subject to the food allergen.

109. (New) The method of claim 108, wherein the exposure to the food allergen is accidental.

110. (New) The method of claim 108, wherein the allergic reaction is a moderate-to-severe allergic reaction.

111. (New) A method of treating a human subject having an allergy to a food allergen, the method comprising:

administering to the subject by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab,

wherein the pharmaceutical composition is administered once about every two weeks, and the dose of omalizumab is from 150 mg to 225 mg, and

wherein body weight of the subject is equal to or greater than 10 kg and less than or equal to

15 kg, and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1850 IU/ml.

112. (New) The method of claim 111, wherein the dose of omalizumab is:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml;

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1500 IU/ml; or

225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml.

113. (New) The method of claim 111, wherein each of the body weight and the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

114. (New) The method of claim 111, wherein the food allergen comprises peanut and one or more of milk, egg, and cashew.

115. (New) The method of claim 111, wherein treating comprises reducing a moderate-to-severe allergic reaction following accidental exposure of the subject to the food allergen.

116. (New) A method of treating a human subject having an allergy to a food allergen, the method comprising:

administering to the subject by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab,

wherein the pharmaceutical composition is administered once about every four weeks, and the dose of omalizumab is from 75 to 150 mg, and

wherein body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 600 IU/ml.

117. (New) The method of claim 116, wherein the dose of omalizumab is:

75 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 300 IU/ml; or

150 mg when the body weight of the subject is greater than or equal to 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml.

118. (New) The method of claim 116, wherein each of the body weight and the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

119. (New) The method of claim 116, wherein the food allergen comprises peanut and one or more of milk, egg, and cashew.

120. (New) The method of claim 116, wherein treating comprises reducing a moderate-to-severe allergic reaction following accidental exposure of the subject to the food allergen.

121. (New) A method of treating a human subject having an allergy to a food allergen and total serum IgE level of greater than or equal to 300 IU/ml and less than or equal to 1850 IU/ml, the method comprising:

administering to the subject by subcutaneous injection once about every four weeks a pharmaceutical composition comprising a dose of omalizumab of:

150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or

administering to the subject by subcutaneous injection once about every two weeks a pharmaceutical composition comprising a dose of omalizumab of:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml;

150 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to

1200 IU/ml; or

225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml.

122. (New) The method of claim 121, wherein each of the body weight and the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

123. (New) The method of claim 121, wherein the food allergen comprises peanut and one or more of milk, egg, and cashew.

124. (New) The method of claim 121, wherein treating comprises reducing a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.

REMARKS

Claims 1-94 were pending in the present application. By virtue of this Preliminary Amendment, Claims 1-94 were canceled, and new Claims 95-124 were added, as shown in the listing of claims. Support for the new claims can be found throughout the specification, original claims and FIG. 2 as filed. Thus, no new matter has been added. After entry of this Preliminary Amendment, Claims 95-124 will be pending, amounting to 30 total claims, including 4 independent claims. Fees for 10 total claims over 20 and fees for 1 independent claim over 3 are submitted herewith.

With respect to any claim amendments or cancellations, Applicant has neither dedicated to the public nor abandoned any unclaimed subject matter. Applicant expressly reserves the right to pursue protection for any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **14639-20668.01**. However, the Commissioner is **not** authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 12, 2023

Respectfully submitted,

By /Christine Lekutis/

Christine Lekutis

Registration No.: 51,934

MORRISON & FOERSTER LLP

425 Market Street

San Francisco, CA 94105-2482

+1 (415) 268-7060



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/486,053	10/12/2023	Ryan Patrick OWEN	14639-20668.01	7842
25226 7590 12/08/2023 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER SZPERKA, MICHAEL EDWARD	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 12/08/2023	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficePA@mofo.com
PatentDocket@mofo.com
pair_mofo@firsttofile.com

DETAILED ACTION

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Applicant's preliminary amendments received October 12, 2023 are acknowledged.

Claims 1-94 have been canceled.

Claims 95-124 have been added.

Claims 95-124 are pending in the instant application.

Election/Restriction

2. This application contains claims directed to the following patentably distinct species of the claimed methods of treating food allergy. For initial prosecution on the merits, applicant to is elect a time interval between administrations and the mass of drug that is administered. Such elections can be made by way or reference to species recited in the claims, such as either two weeks or for weeks between administration as is presently recited in claim 95 for example, or by reference to time intervals fully disclosed in the specification as originally filed but which have not yet been claimed. The species are independent or distinct because they require different process steps, distinct amounts of reagents and presumably distinct patient populations as in general higher masses of drug are administered to adults relative to children. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a serious search and/or examination burden for the patentably distinct species as set forth above because at least one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached Monday-Friday 8:30-5:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Allen can be reached on (571) 270-3497. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka
Primary Examiner
Art Unit 1641

/MICHAEL SZPERKA/
Primary Examiner, Art Unit 1641

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ryan Patrick OWEN

Application No.: 18/486,053

Confirmation No.: 7842

Filed: October 12, 2023

Art Unit: 1641

For: ANTI-IGE ANTIBODY THERAPY FOR
MULTIPLE FOOD ALLERGIES

Examiner: M. E. Szperka

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This is in response to the restriction requirement set forth in the Office Action dated December 8, 2023, for which a response is due on February 8, 2024. Accordingly, this response is timely filed. Applicant hereby elects, *without traverse*, once about every two weeks and a dose of omalizumab of 150 mg as species of the claimed methods.

Amendments to the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

1-94. (Canceled)

95. (Previously Presented) A method of treating a human subject having an allergy to a food allergen, the method comprising:

administering to the subject by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab,

wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is from 150 mg to 225 mg, or the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is from 75 to 150 mg, and

wherein body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than or equal to 30 IU/ml and less than or equal to 1850 IU/ml.

96. (Previously Presented) The method of claim 95, wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml;

150 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml.

97. (Previously Presented) The method of claim 95, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:

75 mg when the body weight of the subject is equal to or greater than 10 kg and less than or

equal to 15 kg, and the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 300 IU/ml.

98. (Previously Presented) The method of claim 95, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:

150 mg when the body weight of the subject is greater than or equal to 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml.

99. (Previously Presented) The method of claim 95, wherein the pharmaceutical composition is administered to a subject having a body weight of greater than or equal to 10 kg and less than or equal to 12 kg at a dose of:

75 mg once about every four weeks if the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 300 IU/ml;

150 mg once about every four weeks if the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; and

150 mg once about every two weeks if the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml.

100. (Previously Presented) The method of claim 95, wherein the pharmaceutical composition is administered to a subject having a body weight of greater than or equal to 12 kg and less than or equal to 15 kg at a dose of:

75 mg once about every four weeks if the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 300 IU/ml;

150 mg once about every four weeks if the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml;

150 mg once about every two weeks if the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; and

225 mg once about every two weeks if the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml.

101. (Previously Presented) The method of claim 95, wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.

102. (Previously Presented) The method of claim 95, wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

103. (Previously Presented) The method of claim 95, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.

104. (Previously Presented) The method of claim 95, wherein the method is not used for emergency treatment of at least one of an allergic reaction to the food allergen and anaphylaxis.

105. (Previously Presented) The method of claim 95, wherein the subject is from 1 year to 5 years of age.

106. (Previously Presented) The method of claim 95, wherein the food allergen comprises peanut.

107. (Previously Presented) The method of claim 106, wherein the food allergen further comprises one or more of milk, egg, and cashew.

108. (Previously Presented) The method of claim 95, wherein treating comprises reducing an allergic reaction following exposure of the subject to the food allergen.

109. (Previously Presented) The method of claim 108, wherein the exposure to the food allergen is accidental.

110. (Previously Presented) The method of claim 108, wherein the allergic reaction is a moderate-to-severe allergic reaction.

111. **(Currently Amended)** A method of treating a human subject having an allergy to a food allergen, the method comprising:

administering to the subject by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab,

wherein the pharmaceutical composition is administered once about every two weeks, and the dose of omalizumab is ~~from 150 mg to 225 mg~~, and

wherein body weight of the subject is equal to or greater than 10 kg and less than or equal to

15 kg, and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 ~~1850~~ IU/ml.

112. **(Currently Amended)** The method of claim 111, wherein the dose of omalizumab is:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1500 IU/ml; ~~or~~

~~—225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml.~~

113. (Previously Presented) The method of claim 111, wherein each of the body weight and the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

114. (Previously Presented) The method of claim 111, wherein the food allergen comprises peanut and one or more of milk, egg, and cashew.

115. (Previously Presented) The method of claim 111, wherein treating comprises reducing a moderate-to-severe allergic reaction following accidental exposure of the subject to the food allergen.

116. (Previously Presented) A method of treating a human subject having an allergy to a food allergen, the method comprising:

administering to the subject by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab,

wherein the pharmaceutical composition is administered once about every four weeks, and the dose of omalizumab is from 75 to 150 mg, and

wherein body weight of the subject is equal to or greater than 10 kg and less than or equal to

15 kg, and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 600 IU/ml.

117. (Previously Presented) The method of claim 116, wherein the dose of omalizumab is:

75 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 30 IU/ml and less than or equal to 300 IU/ml; or

150 mg when the body weight of the subject is greater than or equal to 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml.

118. (Previously Presented) The method of claim 116, wherein each of the body weight and the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

119. (Previously Presented) The method of claim 116, wherein the food allergen comprises peanut and one or more of milk, egg, and cashew.

120. (Previously Presented) The method of claim 116, wherein treating comprises reducing a moderate-to-severe allergic reaction following accidental exposure of the subject to the food allergen.

121. (Previously Presented) A method of treating a human subject having an allergy to a food allergen and total serum IgE level of greater than or equal to 300 IU/ml and less than or equal to 1850 IU/ml, the method comprising:

administering to the subject by subcutaneous injection once about every four weeks a pharmaceutical composition comprising a dose of omalizumab of:

150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or

administering to the subject by subcutaneous injection once about every two weeks a pharmaceutical composition comprising a dose of omalizumab of:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or

equal to 12 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml;

150 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml.

122. (Previously Presented) The method of claim 121, wherein each of the body weight and the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

123. (Previously Presented) The method of claim 121, wherein the food allergen comprises peanut and one or more of milk, egg, and cashew.

124. (Previously Presented) The method of claim 121, wherein treating comprises reducing a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.

REMARKS

The Examiner indicated that pending Claims 95-124 are directed to patentably distinct species. Accordingly, Applicant is required to elect both a time interval between administrations and a mass of drug administered as species for initial prosecution purposes. Applicant hereby elects, *without traverse*, once about every two weeks and a dose of omalizumab of 150 mg as species of the claimed methods.

In addition, Applicant hereby amends Claims 111 and 112. After entry of the amendment, Claims 95-124 remain pending, of which Claims 95, 96, 99-115, and 121-124 encompass the elected species.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **14639-20668.01**. However, the Commissioner is **not** authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 12, 2024

Respectfully submitted,

By /Christine Lekutis/
Christine Lekutis
Registration No.: 51,934
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
+1 (415) 268-7060

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES
<p>As the below named inventor, I hereby declare that:</p> <p>This declaration is directed to: ☐ The attached application, or ☒ United States application or PCT international application number <u>18/486,053</u> filed on <u>10/12/2023</u>.</p> <p>The above-identified application was made or authorized to be made by me.</p> <p>I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.</p> <p>I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.</p> <p style="text-align: center;">WARNING:</p> <p>Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.</p> <p>LEGAL NAME OF INVENTOR</p> <p>Inventor: <u>Ryan Patrick Owen</u> Date (Optional): <u>12-Jan-2024 19:44 CET</u></p> <p>Signature: <u><i>Ryan P. Owen</i></u></p> <p>Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.</p>	

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Attorney Docket No.: 14639-20668.01

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PETITIONER EXHIBIT 1004**Page 101 of 187**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/486,053	10/12/2023	Ryan Patrick OWEN	14639-20668.01	7842
25226 7590 02/01/2024 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER SZPERKA, MICHAEL EDWARD	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 02/01/2024	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficePA@mofo.com
PatentDocket@mofo.com
pair_mofo@firsttofile.com

DETAILED ACTION

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Applicant's response and amendments received January 12, 2024 are acknowledged.

Claims 1-94 have been canceled.

Claims 111 and 112 have been amended.

Claims 95-124 are pending in the instant application.

Applicant's election without traverse of the species of administering omalizumab every two weeks at 150 mg in the reply filed on January 12, 2024 is acknowledged. Upon a review of the art the species election requirement has been withdrawn.

Information Disclosure Statement

2. The IDS form received 12/8/2023 is acknowledged and the references therein have been considered.

Claim Rejections - 35 USC § 102

3. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

(a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

4. Claims 95-124 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Wood et al.

Wood et al. disclose the OUTMATCH clinical trial wherein food allergy patients were administered omalizumab followed by allergen challenge and oral immunotherapy (see entire document and supplemental materials, particularly the abstract, Figure 1 and the Methods section of the paper). Notably omalizumab was administered subcutaneously (see most specifically the final sentence of the first paragraph under "Treatment description" in the right column of page 229). Doses for omalizumab were given according to the dosing chart in Figure E1, which is reproduced herein for applicant's convenience

Supplemental Figure 1: Omalizumab Dosing Table

Baseline IgE {IU/mL}	Body Weight (kg)												
	>10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
≤30-105	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-200	75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300	75	75	150	150	150	225	300	300	450	450	450	600	375
>300-400	150	150	150	225	225	300	450	450	450	600	600	450	525
>400-500	150	150	225	225	300	450	450	600	600	375	375	525	600
>500-600	150	150	225	300	300	450	600	600	375	450	450	600	
>600-700	150	150	225	300	225	450	600	375	450	450	525		
>700-800	150	150	150	225	225	300	375	450	450	525	600		
>800-900	150	150	150	225	225	300	375	450	525	600			
>900-1000	150	150	225	225	300	375	450	525	600				
>1000-1100	150	150	225	225	300	375	450	600					
>1100-1200	150	150	225	300	300	450	525	600					
>1200-1300	150	225	225	300	375	450	525						
>1300-1500	150	225	300	300	375	525	600						
>1500-1850		225	300	375	450	600							

Dosing frequency:

☐	Dose every 4 weeks
☐	Dose every 2 weeks
☐	Do not dose

Note that the administered dose is based upon the patient's body weight and baseline serum IgE. This chart clearly shows that patients between 10-15 kg with an IgE of 30-

1850 IU/mL will receive 75 or 150 mg every 4 weeks or 150 or 225 mg every 2 weeks, with patients having higher initial IgE titer receiving larger amounts of omalizumab more often as per the chart. For example, the chart indicates that administration of 150 mg every two weeks is used in patients who are 10-12 kg and have IgE of 600-1500, while 225 mg omalizumab every two weeks is used in patients between 12-15 kg with a serum IgE of 1200-1850. Note that as per Figure 1, during stage 1 which lasts 16-20 weeks (and an additional 24-48 weeks in the open label extension arm), patients receive omalizumab and do not also receive oral immunotherapy. Further, in stage 2, many patients do not receive oral immunotherapy with the food allergen as they are given placebo (i.e. they are still receiving omalizumab monotherapy even if they don't know that). Food allergens to which the patients may be sensitized prior to beginning the study include peanut and at least two more such as from milk, egg, wheat and other nuts, and patients within the recited range of 1-5 years are included in the study patient population (see particularly the first paragraph of the Methods section).

Therefore, the prior art anticipates the instant claimed invention.

5. Claims 95-124 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by CONSORTIUM FOR FOOD ALLERGY RESEARCH ("Protocol CoOFAR-11 Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults OUtMATCH", Version 6.0 dated June 13, 2022, supplied as reference 37 on the 12/8/2023 IDS, hereafter "CoOFAR")

CoOFAR disclose the OUtMATCH clinical trial wherein food allergy patients were administered omalizumab followed by allergen challenge and oral immunotherapy (see entire document, particularly the protocol synopsis beginning on page 4). Notably omalizumab was administered subcutaneously with doses for omalizumab given based on patient body mass and baseline IgE according to the dosing chart reproduced herein for applicant's convenience (see also pages 15 and 130 of the document)

Appendix 2: Omalizumab Dosing Table

Baseline IgE (IU/mL)	Body Weight (kg)												
	<10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
<30-100	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-200	75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300	75	75	150	150	150	225	300	300	450	450	450	600	375
>300-400	150	150	150	150	225	300	450	450	450	600	600	450	525
>400-500	150	150	225	225	300	450	450	600	600	375	375	525	600
>500-600	150	150	225	300	300	450	600	600	375	450	450	600	
>600-700	150	150	225	300	225	450	600	375	450	450	525		
>700-800	150	150	150	225	225	300	375	450	450	525	600		
>800-900	150	150	150	225	225	300	375	450	450	525	600		
>900-1000	150	150	225	225	300	375	450	525	600				
>1000-1100	150	150	225	225	300	375	450	600					
>1100-1200	150	150	225	300	300	450	525	600					
>1200-1300	150	225	225	300	375	450	525						
>1300-1400	150	225	300	300	375	525	600						
>1400-1500		225	300	375	450	600							

Dosing frequency:

	Dose every 4 weeks
	Dose every 2 weeks
	Do not dose

Note that the administered dose is based upon the patient's body weight and baseline serum IgE. This chart clearly shows that patients between 10-15 kg with an IgE of 30-1850 IU/mL will receive 75 or 150 mg every 4 weeks or 150 or 225 mg every 2 weeks, with patients having higher initial IgE titer receiving larger amounts of omalizumab more often as per the chart. For example, the chart indicates that administration of 150 mg every two weeks is used in patients who are 10-12 kg and have IgE of 600-1500, while 225 mg omalizumab every two weeks is used in patients between 12-15 kg with a serum IgE of 1200-1850. Note that as described in the Study Design section (beginning on page 7), during stage 1 which lasts 16 weeks (and an additional 24-48 weeks in the open label extension arm), patients receive omalizumab and do not also receive oral immunotherapy. Further, in stage 2, many patients do not receive oral immunotherapy with the food allergen as they are given placebo (i.e. they are still receiving omalizumab monotherapy even if they don't know that). Food allergens to which the patients may be sensitized prior to beginning the study include peanut and at least two more such as from milk, egg, wheat and other nuts, and patients within the recited range of 1-5 years

are included in the study patient population (see particularly the Inclusion Criteria beginning on page 15).

Therefore, the prior art anticipates the instant claimed invention.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal

Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

7. Claims 95-124 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 10,034,940 in view of Wood et al. and/or CONSORTIUM FOR FOOD ALLERGY RESEARCH ("Protocol CoOFAR-11 Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults OUTMATCH", Version 6.0 dated June 13, 2022, supplied as reference 37 on the 12/8/2023 IDS, hereafter "CoOFAR")

The issued claims recite methods of treating an IgE-mediated disorder by administering rhuMabE25 (aka omalizumab, XOLAIR, see all issued claims). The issued claims indicate that such administration is subcutaneous (see claims 23 and 24 in particular) and that the IgE mediated disorder is food allergy, including peanut allergy (see particularly claims 9-12). Such claims differ from the instant claimed invention in that neither the mass of omalizumab administered nor the time interval between administrations is recited.

Wood et al. disclose the OUTMATCH clinical trial wherein food allergy patients were administered omalizumab followed by allergen challenge and oral immunotherapy (see entire document and supplemental materials, particularly the abstract, Figure 1 and the Methods section of the paper). Notably omalizumab was administered subcutaneously (see most specifically the final sentence of the first paragraph under "Treatment description" in the right column of page 229). Doses for omalizumab were given according to the dosing chart in Figure E1, which is reproduced herein for applicant's convenience

Supplemental Figure 1: Omalizumab Dosing Table

Baseline IgE {IU/mL}	Body Weight (kg)												
	≤10-12	> 12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
≤30-100	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-200	75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300	75	75	150	150	150	225	300	300	450	450	450	600	375
>300-400	150	150	150	225	225	300	450	450	450	600	600	450	525
>400-500	150	150	225	225	300	450	450	600	600	375	375	525	600
>500-600	150	150	225	300	300	450	600	600	375	450	450	600	
>600-700	150	150	225	300	225	450	500	375	450	450	525		
>700-800	150	150	150	225	225	300	375	450	450	525	500		
>800-900	150	150	150	225	225	300	375	450	525	500			
>900-1000	150	150	225	225	300	375	450	525	600				
>1000-1100	150	150	225	225	300	375	450	600					
>1100-1200	150	150	225	300	300	450	525	500					
>1200-1300	150	225	225	300	375	450	525						
>1300-1500	150	225	300	300	375	525	500						
>1500-1850		225	300	375	450	600							

Dosing frequency:

☐	Dose every 4 weeks
☐	Dose every 2 weeks
☐	Do not dose

Note that the administered dose is based upon the patient's body weight and baseline serum IgE. This chart clearly shows that patients between 10-15 kg with an IgE of 30-1850 IU/mL will receive 75 or 150 mg every 4 weeks or 150 or 225 mg every 2 weeks, with patients having higher initial IgE titer receiving larger amounts of omalizumab more often as per the chart. For example, the chart indicates that administration of 150 mg every two weeks is used in patients who are 10-12 kg and have IgE of 600-1500, while 225 mg omalizumab every two weeks is used in patients between 12-15 kg with a serum IgE of 1200-1850. Note that as per Figure 1, during stage 1 which lasts 16-20 weeks (and an additional 24-48 weeks in the open label extension arm), patients receive omalizumab and do not also receive oral immunotherapy. Further, in stage 2, many patients do not receive oral immunotherapy with the food allergen as they are given placebo (i.e. they are still receiving omalizumab monotherapy even if they don't know that). Food allergens to which the patients may be sensitized prior to beginning the study include peanut and at least two more such as from milk, egg, wheat and other nuts, and patients within the recited range of 1-5 years are included in the study patient population (see particularly the first paragraph of the Methods section).

CoOFAR disclose the OUtMATCH clinical trial wherein food allergy patients were administered omalizumab followed by allergen challenge and oral immunotherapy (see entire document, particularly the protocol synopsis beginning on page 4). Notably omalizumab was administered subcutaneously with doses for omalizumab given based on patient body mass and baseline IgE according to the dosing chart reproduced herein for applicant's convenience (see also pages 15 and 130 of the document)

Appendix 2: Omalizumab Dosing Table

	Body Weight (kg)												
Baseline IgE (IU/mL)	<10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-180
<30-100	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-300	75	75	75	150	150	150	300	300	300	300	300	450	600
>300-600	75	75	150	150	150	375	300	300	450	450	450	600	375
>600-900	150	150	150	225	225	300	450	450	450	600	600	450	525
>900-1200	150	150	225	300	300	450	600	600	375	450	450	600	
>1200-1500	150	150	225	300	225	450	600	375	450	450	525		
>1500-1850	150	150	225	225	300	375	450	375	450	470	525	600	
>1850-2150	150	150	225	225	225	375	375	450	525	600			
>2150-2450	150	150	225	225	300	375	450	525	600				
>2450-2750	150	150	225	225	300	375	450	600					
>2750-3050	150	150	225	225	300	375	450	600					
>3050-3350	150	150	225	225	300	375	450	600					
>3350-3650	150	150	225	225	300	375	450	600					
>3650-3950	150	150	225	225	300	375	450	600					
>3950-4250	150	150	225	225	300	375	450	600					
>4250-4550	150	150	225	225	300	375	450	600					
>4550-4850	150	150	225	225	300	375	450	600					
>4850-5150	150	150	225	225	300	375	450	600					
>5150-5450	150	150	225	225	300	375	450	600					
>5450-5750	150	150	225	225	300	375	450	600					
>5750-6050	150	150	225	225	300	375	450	600					
>6050-6350	150	150	225	225	300	375	450	600					
>6350-6650	150	150	225	225	300	375	450	600					
>6650-6950	150	150	225	225	300	375	450	600					
>6950-7250	150	150	225	225	300	375	450	600					
>7250-7550	150	150	225	225	300	375	450	600					
>7550-7850	150	150	225	225	300	375	450	600					
>7850-8150	150	150	225	225	300	375	450	600					
>8150-8450	150	150	225	225	300	375	450	600					
>8450-8750	150	150	225	225	300	375	450	600					
>8750-9050	150	150	225	225	300	375	450	600					
>9050-9350	150	150	225	225	300	375	450	600					
>9350-9650	150	150	225	225	300	375	450	600					
>9650-9950	150	150	225	225	300	375	450	600					
>9950-10250	150	150	225	225	300	375	450	600					
>10250-10550	150	150	225	225	300	375	450	600					
>10550-10850	150	150	225	225	300	375	450	600					
>10850-11150	150	150	225	225	300	375	450	600					
>11150-11450	150	150	225	225	300	375	450	600					
>11450-11750	150	150	225	225	300	375	450	600					
>11750-12050	150	150	225	225	300	375	450	600					
>12050-12350	150	150	225	225	300	375	450	600					
>12350-12650	150	150	225	225	300	375	450	600					
>12650-12950	150	150	225	225	300	375	450	600					
>12950-13250	150	150	225	225	300	375	450	600					
>13250-13550	150	150	225	225	300	375	450	600					
>13550-13850	150	150	225	225	300	375	450	600					
>13850-14150	150	150	225	225	300	375	450	600					
>14150-14450	150	150	225	225	300	375	450	600					
>14450-14750	150	150	225	225	300	375	450	600					
>14750-15050	150	150	225	225	300	375	450	600					
>15050-15350	150	150	225	225	300	375	450	600					
>15350-15650	150	150	225	225	300	375	450	600					
>15650-15950	150	150	225	225	300	375	450	600					
>15950-16250	150	150	225	225	300	375	450	600					
>16250-16550	150	150	225	225	300	375	450	600					
>16550-16850	150	150	225	225	300	375	450	600					
>16850-17150	150	150	225	225	300	375	450	600					
>17150-17450	150	150	225	225	300	375	450	600					
>17450-17750	150	150	225	225	300	375	450	600					
>17750-18050	150	150	225	225	300	375	450	600					
>18050-18350	150	150	225	225	300	375	450	600					
>18350-18650	150	150	225	225	300	375	450	600					
>18650-18950	150	150	225	225	300	375	450	600					
>18950-19250	150	150	225	225	300	375	450	600					
>19250-19550	150	150	225	225	300	375	450	600					
>19550-19850	150	150	225	225	300	375	450	600					
>19850-20150	150	150	225	225	300	375	450	600					
>20150-20450	150	150	225	225	300	375	450	600					
>20450-20750	150	150	225	225	300	375	450	600					
>20750-21050	150	150	225	225	300	375	450	600					
>21050-21350	150	150	225	225	300	375	450	600					
>21350-21650	150	150	225	225	300	375	450	600					
>21650-21950	150	150	225	225	300	375	450	600					
>21950-22250	150	150	225	225	300	375	450	600					
>22250-22550	150	150	225	225	300	375	450	600					
>22550-22850	150	150	225	225	300	375	450	600					
>22850-23150	150	150	225	225	300	375	450	600					
>23150-23450	150	150	225	225	300	375	450	600					
>23450-23750	150	150	225	225	300	375	450	600					
>23750-24050	150	150	225	225	300	375	450	600					
>24050-24350	150	150	225	225	300	375	450	600					
>24350-24650	150	150	225	225	300	375	450	600					
>24650-24950	150	150	225	225	300	375	450	600					
>24950-25250	150	150	225	225	300	375	450	600					
>25250-25550	150	150	225	225	300	375	450	600					
>25550-25850	150	150	225	225	300	375	450	600					
>25850-26150	150	150	225	225	300	375	450	600					
>26150-26450	150	150	225	225	300	375	450	600					
>26450-26750	150	150	225	225	300	375	450	600					
>26750-27050	150	150	225	225	300	375	450	600					
>27050-27350	150	150	225	225	300	375	450	600					
>27350-27650	150	150	225	225	300	375	450	600					
>27650-27950	150	150	225	225	300	375	450	600					
>27950-28250	150	150	225	225	300	375	450	600					
>28250-28550	150	150	225	225	300	375	450	600					
>28550-28850	150	150	225	225	300	375	450	600					
>28850-29150	150	150	225	225	300	375	450	600					
>29150-29450	150	150	225	225	300	375	450	600					
>29450-29750	150	150	225	225	300	375	450	600					
>29750-30050	150	150	225	225	300	375	450	600					
>30050-30350	150	150	225	225	300	375	450	600					
>30350-30650	150	150	225	225	300	375	450	600					
>30650-30950	150	150	225	225	300	375	450	600					
>30950-31250	150	150	225	225	300	375	450	600					
>31250-31550	150	150	225	225	300	375	450	600					
>31550-31850	150	150	225	225	300	375	450	600					
>31850-32150	150	150	225	225	300	375	450	600					
>32150-32450	150	150	225	225	300	375	450	600					
>32450-32750	150	150	225	225	300	375	450	600					
>32750-													

open label extension arm), patients receive omalizumab and do not also receive oral immunotherapy. Further, in stage 2, many patients do not receive oral immunotherapy with the food allergen as they are given placebo (i.e. they are still receiving omalizumab monotherapy even if they don't know that). Food allergens to which the patients may be sensitized prior to beginning the study include peanut and at least two more such as from milk, egg, wheat and other nuts, and patients within the recited range of 1-5 years are included in the study patient population (see particularly the Inclusion Criteria beginning on page 15).

Therefore, it would have been obvious to ordinary artisans that the precise dosing information as disclosed by Wood et al. and/or CoOFAR could be used when practicing the administration methods of the issued claims. It would be obvious to artisans that in order to actually administer a drug to a patient, the artisan must know how much drug to give and when to give it, and such information is detailed in the protocol disclosed by Wood et al. and/or CoOFAR, and given that the issued claims recite such administration to treat the disease artisans would reasonably expect much more than a reasonable expectation of success in treating food allergy via subcutaneous administration of omalizumab.

It should be noted that while Ryan Owen is not an inventor of the '940 patent, both the issued patent and instant application are assigned to Genentech. If this information is incorrect, applicant is requested to clarify the record.

8. Claims 95-124 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 8,961,964 in view of Wood et al. and/or

The issued claims recite stable formulations of an anti-IgE antibody in pre-filled syringes, wherein the antibody is recited as having the heavy and light chains of the e25 antibody, better known as omalizumab/XOLAIR (see all issued claims as well as the sequence listing and specification for the definition of SEQ ID NOs:1 and 4). Such claims differ from the present claimed invention in that no methods of treatment, for food allergy or any other IgE-mediated disorder, are recited in the issued claims.

Wood et al. disclose the OUTMATCH clinical trial wherein food allergy patients were administered omalizumab followed by allergen challenge and oral immunotherapy (see entire document and supplemental materials, particularly the abstract, Figure 1 and the Methods section of the paper). Notably omalizumab was administered subcutaneously (see most specifically the final sentence of the first paragraph under "Treatment description" in the right column of page 229). Doses for omalizumab were given according to the dosing chart in Figure E1, which is reproduced herein for applicant's convenience

Supplemental Figure 1: Omalizumab Dosing Table

Baseline IgE {IU/mL}	Body Weight (kg)												
	210-12	> 12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
230-130	75	75	75	75	75	75	150	150	150	150	150	300	300
>150-200	75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300	75	75	150	150	150	225	300	300	450	450	450	600	375
>300-400	150	150	150	225	225	300	450	450	450	600	600	450	525
>400-500	150	150	225	325	300	450	450	600	600	375	375	525	600
>500-600	150	150	225	300	300	450	500	600	375	450	450	500	
>600-700	150	150	225	300	225	450	600	375	450	450	525		
>700-800	150	150	150	225	225	300	375	450	450	525	600		
>800-900	150	150	150	225	225	300	375	450	525	600			
>900-1000	150	150	225	225	300	375	450	525	600				
>1000-1100	150	150	225	225	300	375	450	600					
>1100-1200	150	150	225	300	300	450	525	600					
>1200-1300	150	225	225	300	375	450	525						
>1300-1500	150	225	300	300	375	525	600						
>1500-1850		225	300	375	450	600							

Dosing frequency:

☐	Dose every 4 weeks
☐	Dose every 2 weeks
☐	Do not dose

Note that the administered dose is based upon the patient's body weight and baseline serum IgE. This chart clearly shows that patients between 10-15 kg with an IgE of 30-1850 IU/mL will receive 75 or 150 mg every 4 weeks or 150 or 225 mg every 2 weeks, with patients having higher initial IgE titer receiving larger amounts of omalizumab more often as per the chart. For example, the chart indicates that administration of 150 mg every two weeks is used in patients who are 10-12 kg and have IgE of 600-1500, while 225 mg omalizumab every two weeks is used in patients between 12-15 kg with a serum IgE of 1200-1850. Note that as per Figure 1, during stage 1 which lasts 16-20

weeks (and an additional 24-48 weeks in the open label extension arm), patients receive omalizumab and do not also receive oral immunotherapy. Further, in stage 2, many patients do not receive oral immunotherapy with the food allergen as they are given placebo (i.e. they are still receiving omalizumab monotherapy even if they don't know that). Food allergens to which the patients may be sensitized prior to beginning the study include peanut and at least two more such as from milk, egg, wheat and other nuts, and patients within the recited range of 1-5 years are included in the study patient population (see particularly the first paragraph of the Methods section).

CoOFAR disclose the OUtMATCH clinical trial wherein food allergy patients were administered omalizumab followed by allergen challenge and oral immunotherapy (see entire document, particularly the protocol synopsis beginning on page 4). Notably omalizumab was administered subcutaneously with doses for omalizumab given based on patient body mass and baseline IgE according to the dosing chart reproduced herein for applicant's convenience (see also pages 15 and 130 of the document)

Appendix 2: Omalizumab Dosing Table

Baseline IgE (IU/ml)	Body Weight (kg)												
	<10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
<100-100	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-200	75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300	75	75	150	150	150	150	300	300	300	450	450	600	600
>300-400	150	150	150	150	150	150	300	300	300	450	450	600	600
>400-500	150	150	150	150	150	150	300	300	300	450	450	600	600
>500-600	150	150	150	150	150	150	300	300	300	450	450	600	600
>600-700	150	150	150	150	150	150	300	300	300	450	450	600	600
>700-800	150	150	150	150	150	150	300	300	300	450	450	600	600
>800-900	150	150	150	150	150	150	300	300	300	450	450	600	600
>900-1000	150	150	150	150	150	150	300	300	300	450	450	600	600
>1000-1100	150	150	150	150	150	150	300	300	300	450	450	600	600
>1100-1200	150	150	150	150	150	150	300	300	300	450	450	600	600
>1200-1300	150	150	150	150	150	150	300	300	300	450	450	600	600
>1300-1400	150	150	150	150	150	150	300	300	300	450	450	600	600
>1400-1500	150	150	150	150	150	150	300	300	300	450	450	600	600

Dosing frequency:

☐	Dose every 4 weeks
☐	Dose every 2 weeks
☐	Do not dose

Note that the administered dose is based upon the patient's body weight and baseline serum IgE. This chart clearly shows that patients between 10-15 kg with an IgE of 30-1850 IU/mL will receive 75 or 150 mg every 4 weeks or 150 or 225 mg every 2 weeks, with patients having higher initial IgE titer receiving larger amounts of omalizumab more often as per the chart. For example, the chart indicates that administration of 150 mg every two weeks is used in patients who are 10-12 kg and have IgE of 600-1500, while 225 mg omalizumab every two weeks is used in patients between 12-15 kg with a serum IgE of 1200-1850. Note that as described in the Study Design section (beginning on page 7), during stage 1 which lasts 16 weeks (and an additional 24-48 weeks in the open label extension arm), patients receive omalizumab and do not also receive oral immunotherapy. Further, in stage 2, many patients do not receive oral immunotherapy with the food allergen as they are given placebo (i.e. they are still receiving omalizumab monotherapy even if they don't know that). Food allergens to which the patients may be sensitized prior to beginning the study include peanut and at least two more such as from milk, egg, wheat and other nuts, and patients within the recited range of 1-5 years are included in the study patient population (see particularly the Inclusion Criteria beginning on page 15).

Therefore, it would have been obvious to ordinary artisans that products of the issued claims could be used in the food allergy treatment methods disclosed by Wood et al. and/or CoOFAR, especially as the claimed product and the product used in the methods of Wood et al. and/or CoOFAR are both omalizumab.

It should be pointed out that the issued claims are drawn to products, whereas the instant claimed inventions are methods of using a product. Further, the application which gave rise to the issued patent is in a different lineage completely unconnected to the instant application as can be readily seen by inspection of the filing receipt mailed 10/25/2023:

Domestic Priority data as claimed by applicant

This application is a CON of PCT/US2023/070639 07/20/2023
which claims benefit of 63/512,051 07/05/2023

As has been made abundantly clear in recent court decisions, including *Pfizer v. Teva* and *Amgen Inc. v. F. Hoffman-La-Roche Ltd.*, "the § 121 safe harbor provision does not protect continuation applications or patents descending from only continuation

applications. The statute on its face applies only to divisional applications, and a continuation application, like a continuation-in-part application, is not a divisional application.” Given that the instant application is not a divisional of the application which gave rise to the issued patent, any restriction requirements (or the lack thereof) appearing in unrelated lineages do not serve to shield the instant application, and therefore the instant rejection has been set forth.

Further, it should be noted that while Ryan Owen is not an inventor of the ‘964 patent, both the issued patent and instant application are assigned to Genentech. If this information is incorrect, applicant is requested to clarify the record.

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached Monday-Friday 8:30-5:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197

Application/Control Number: 18/486,053
Art Unit: 1641

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(toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka
Primary Examiner
Art Unit 1641

/MICHAEL SZPERKA/
Primary Examiner, Art Unit 1641



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/486,053	10/12/2023	Ryan Patrick OWEN	14639-20668.01	7842
25226 7590 04/10/2024 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER SZPERKA, MICHAEL EDWARD	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 04/10/2024	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficePA@mofo.com
PatentDocket@mofo.com
pair_mofo@firsttofile.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 18/486,053	Applicant(s) OWEN, Ryan Patrick		
	Examiner Michael Szperka	Art Unit 1641	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
Michael Szperka	Primary Examiner	Video Conference
Christine Lekutis	Attorney of Record	
Jie Zhou	Attorney of Record	

Date of Interview: 05 April 2024

Issues Discussed:

35 U.S.C. 102

Applicant wished to discuss potential strategies to overcome the rejections of record as the cited prior art NPL documents fall within the grace period. No agreement was reached concerning exactly how applicant would overcome the rejection of record.

/MICHAEL SZPERKA/ Primary Examiner, Art Unit 1641	
<p>Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04</p> <p>Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing</p>	

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

EXHIBIT A

Docket No.: 14639-20668.01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ryan Patrick OWEN

Application No.: 18/486,053

Confirmation No.: 7842

Filed: October 12, 2023

Art Unit: 1641

For: ANTI-IGE ANTIBODY THERAPY FOR
MULTIPLE FOOD ALLERGIES

Examiner: M. E. Szperka

DECLARATION OF AHMAR IQBAL UNDER 37 C.F.R. § 1.130(a)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

I, Ahmar Iqbal, M.D. (M.B., B.S.), declare as follows:

1. I am named as an inventor of U.S. Application No. 18/486,053 (the “Application”) and am familiar with the contents thereof, including the pending claims. Ryan Patrick Owen and Robert A. Wood are also named as inventors of the Application.

2. I am an Executive Medical Director, U.S. Medical Affairs, at Genentech, Inc. (hereinafter “Genentech”), of South San Francisco, California.

3. Genentech is an assignee of the Application.

4. I am a co-author of Wood et al., “Protocol design and synopsis: omalizumab as monotherapy and as adjunct therapy to multiallergen OIT in children and adults with food allergy (OUtMATCH)” J. Allergy Clin. Immunol. Global, 1(4): 225-232, ePub. July 21, 2022 (hereinafter “Wood Publication”). Co-inventor Robert A. Wood is also a co-author of the Wood Publication.

sf-5869505

Application No.: 18/486,053

Docket No.: 14639-20668.01

5. The Wood Publication discloses subject matter pertaining to the Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults,” or “OUtMATCH,” a Phase 3 clinical trial investigating the safety and efficacy of treating patients with multiple food allergies by administering omalizumab. OUtMATCH was developed as a collaboration between the Consortium for Food Allergy Research (“CoFAR”), the National Institute of Allergy and Infectious Diseases (NIAID), Genentech, and Novartis.¹

6. Ryan Patrick Owen, Robert A. Wood and I were the sole contributors to the Wood Publication as it relates to the subject matter of the pending claims, and this subject matter was provided to the other authors named on the Wood Publication. The other authors named on the Wood Publication, R. Sharon Chinthrajah, Amanda K. Rudman Spergel, Denise C. Babineau, Scott H. Sicherer, Edwin H. Kim, Wayne G. Shreffler, Stacie M. Jones, Donald Y. M. Leung, Brian P. Vickery, J. Andrew Bird, Jonathan M. Spergel, Michael Kulis, Derrick Kaufman, Dale T. Umetsu, Monica Ligueros-Saylan, Alkaz Uddin, Robert B. Fogel, Stephanie Lussier, Kim Mudd, Julian Poyser, Martin MacPhee, Maria Veri, Wendy Davidson, Sanaz Hamrah, Andrew Long, and Alkis Togias did not contribute to the subject matter of the pending claims, but did contribute to other aspects of the clinical trial protocol and/or administration or execution of the clinical trial. The other authors are not co-inventors of the subject matter of the pending claims.

7. Thus, to the extent the Wood Publication described the subject matter of the pending claims, the Wood Publication described the work of the inventors.

8. The “Protocol CoFAR-11 Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults OUtMATCH, Version 6.0/13Jun2022” document (the “Protocol Document”) was published online by the National Institute of Allergy and Infectious Diseases (NIAID) on February 23, 2023. Co-inventor Robert A. Wood is a co-author of the Protocol Document.

9. Ryan Patrick Owen, Robert A. Wood and I were the sole contributors to the Protocol Document as it relates to the subject matter of the pending claims, and this subject matter was provided to the other authors named on the Protocol Document. The other authors

¹ Wood Publication, abstract, pages 225-226.

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named on the Protocol Document, Sharon Chinthrajah, Lisa Wheatley, Julian Poyser, Sanaz Hamrah, Maria Veri and Nancy Yovetich did not contribute to the subject matter of the pending claims, but did contribute to other aspects of the clinical trial protocol and/or administration or execution of the clinical trial. The other authors are not co-inventors of the subject matter of the pending claims.

10. Thus, to the extent the Protocol Document described the subject matter of the pending claims, the Protocol Document described the work of the inventors.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

11-Apr-2024 | 11:05 PDT

Date

Ahmar Iqbal

Ahmar Iqbal, M.D. (M.B., B.S.)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ryan Patrick OWEN

Application No.: 18/486,053

Confirmation No.: 7842

Filed: October 12, 2023

Art Unit: 1641

For: ANTI-IGE ANTIBODY THERAPY FOR
MULTIPLE FOOD ALLERGIES

Examiner: M. E. Szperka

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION
UNDER 37 C.F.R. 1.111

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

INTRODUCTORY COMMENTS

This is in response to the non-final Office Action dated February 1, 2024, for which a response is due on May 1, 2024. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the remarks presented herein are respectfully requested.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims, which begins on page 3 of this paper.

Amendments to the Drawings begin on page 10 of this paper.

Remarks/Arguments begin on page 11 of this paper.

sf-5747864

AMENDMENTS TO THE SPECIFICATION

Please add the following new heading and paragraph after the Cross-Reference to Related Applications paragraph [0001]:

**STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT**

[0001.1] This invention was made with government support under cooperative agreements, AI130836 and AI130838, awarded by the National Institutes of Health (NIH). The government has certain rights in the invention.

Please replace paragraph [0029] with the following amended paragraph:

[0029] Omalizumab (CAS Registry No. 242138-07-4) is a recombinant DNA-derived, humanized IgG1 monoclonal antibody with a molecular weight of approximately 149 kDa that selectively binds to human IgE. The amino acid sequences of the heavy chain variable region (VH) and the light chain variable region (VL) of omalizumab are shown as the E25 sequences in Figure 2 of U.S. Patent No. 6,172,213, and are set forth herein as SEQ ID NO:3 and SEQ ID NO:4. ~~SEQ ID NO:1~~ and ~~SEQ ID NO:2~~, respectively. The amino acid sequences of the full length heavy chain and the full length light chain of omalizumab are shown as the E25 sequences in Figure 12 of U.S. Patent No. 6,172,213, and are set forth herein as SEQ ID NO:1 and SEQ ID NO:2. ~~SEQ ID NO:3~~ and ~~SEQ ID NO:4~~, respectively.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application.

1-94. (Canceled)

95. **(Currently Amended)** A method of treating a human subject having an allergy to a food allergen, the method comprising:

administering to the subject by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab,

wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is from 150 mg to 225 mg, or the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is from 75 mg to 150 mg, and

wherein body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is ~~greater than or equal to~~ or greater than 30 IU/ml and less than or equal to 1850 IU/ml.

96. **(Currently Amended)** The method of claim 95, wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; or

150 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

97. **(Currently Amended)** The method of claim 95, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:

75 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

98. **(Currently Amended)** The method of claim 95, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:

150 mg when the body weight of the subject is equal to or greater than ~~or equal to~~ 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

99. **(Canceled)**

100. **(Currently Amended)** The method of claim 95, wherein the pharmaceutical composition is administered to a subject having a body weight of greater than ~~or equal to~~ 12 kg and less than or equal to 15 kg at a dose of:

75 mg once about every four weeks if the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml; or

150 mg once about every four weeks if the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or

150 mg once about every two weeks if the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or[[and]]

225 mg once about every two weeks if the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

101. **(Currently Amended)** The method of claim 96[[95]], wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.

102. **(Canceled)**

103. **(Currently Amended)** The method of claim 96[[95]], wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.

104-107. **(Canceled)**

108. **(Currently Amended)** The method of claim 96[[95]], wherein treating comprises reducing an allergic reaction following accidental exposure of the subject to the food allergen.

109. **(Canceled)**

110. **(Currently Amended)** The method of claim 96[[108]], wherein treating comprises reducing the allergic reaction is a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.

111. **(Canceled)**

112. **(Currently Amended)** The method of claim 95[[111]], wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is:

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1500 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

113-116. **(Canceled)**

117. **(Currently Amended)** The method of claim 95[[116]], wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:

75 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml; or

150 mg when the body weight of the subject is equal to or greater than~~or equal to~~ 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

118-120. **(Canceled)**

121. **(Currently Amended)** A method of treating a human subject having an allergy to a food allergen ~~and total serum IgE level of greater than or equal to 300 IU/ml and less than or equal to 4850 IU/ml~~, the method comprising:

(i) administering to the subject by subcutaneous injection once about every four weeks a pharmaceutical composition comprising a dose of omalizumab of:

150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and ~~the~~ total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or

(ii) administering to the subject by subcutaneous injection once about every two weeks a pharmaceutical composition comprising a dose of omalizumab of:

150 mg when ~~the~~ body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and ~~the~~ total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; or

150 mg when ~~the~~ body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and ~~the~~ total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

225 mg when ~~the~~ body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and ~~the~~ total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

122. **(Currently Amended)** The method of claim 121, wherein ~~each of the body weight and the total serum IgE level~~ of the subject is determined prior to administration of a first dose of omalizumab.

123. **(Canceled)**

124. **(Previously Presented)** The method of claim 121, wherein treating comprises reducing a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.

125. **(New)** The method of claim 121, wherein treating comprises reducing an allergic reaction following accidental exposure of the subject to the food allergen.

126. **(New)** The method of claim 121, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.

127. **(New)** A method of treating a human subject having an allergy to a food allergen, the method comprising:

(i) administering to the subject by subcutaneous injection once about every four weeks a pharmaceutical composition comprising a dose of omalizumab of:

75 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml; or

150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or

(ii) administering to the subject by subcutaneous injection once about every two weeks a pharmaceutical composition comprising a dose of omalizumab of:

150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; or

150 mg when body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or

225 mg when body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

128. **(New)** The method of claim 127, wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.

129. **(New)** The method of claim 127, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.

130. **(New)** The method of claim 127, wherein the subject is from 1 year to 5 years of age.

131. **(New)** The method of claim 127, wherein the subject has an allergy to peanut and to one or more of milk, egg, and cashew.

132. **(New)** The method of claim 127, wherein treating comprises reducing an allergic reaction following exposure of the subject to the food allergen.

133. **(New)** The method of claim 132, wherein the exposure to the food allergen is accidental.

134. **(New)** The method of claim 132, wherein the allergic reaction is a moderate-to-severe allergic reaction.

135. **(New)** A method of treating a human subject having an allergy to a food allergen, the method comprising:

administering to the subject having a body weight equal to or greater than 10 kg and less than or equal to 12 kg by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab of:

75 mg once about every four weeks if total serum IgE level of the subject is equal to or

greater than 30 IU/ml and less than or equal to 300 IU/ml; or

150 mg once about every four weeks if total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or

150 mg once about every two weeks if total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; and

wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

136. **(New)** The method of claim 135, wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.

137. **(New)** The method of claim 135, wherein treating comprises reducing a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.

138. **(New)** The method of claim 135, wherein treating comprises reducing an allergic reaction following accidental exposure of the subject to the food allergen.

139. **(New)** The method of claim 135, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.

Doc Code: R48.REQ

Document Description: Request under Rule 48 correcting inventorship

PTO/AIA/40 (04-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)	Application Number	18/486,053
	Filing Date	October 12, 2023
	First Named Inventor	Ryan Patrick OWEN
	Art Unit	1641
	Examiner Name	M. E. Szperka
	Practitioner Docket Number	14639-20668.01

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicant hereby requests that the inventorship be corrected or changed, or that the name of the inventor or a joint inventor, or the order of the names of joint inventors, be changed, in the above-identified application. **Note:** 37 CFR 1.48 applies to any request to correct inventorship filed on or after September 16, 2012, regardless of the application filing date. **Do not submit this form after payment of the issue fee or if the application has been patented.** See 37 CFR 1.324 for correction of inventorship in a patent.

Please check the applicable box(es) below.

For a nonprovisional application:

- ☒ 1. This request is to correct or change the inventorship in a **nonprovisional** application (**under 37 CFR 1.48(a)**) and includes:
- ☒ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) with the corrected or updated information shown with markings (e.g., underlining for insertions, strikethrough for deletions). See the Manual of Patent Examining Procedure (MPEP) section 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).
- ☒ The processing fee set forth in 37 CFR 1.17(i). \$ **140.00**
- ☒ An inventor is being added. An inventor's oath or declaration by any actual inventor who has not yet executed an oath or declaration is required (see 37 CFR 1.48(b)). See MPEP 602.01(a) for information about an inventor's oath or declaration for an application filed on/after September 16, 2012 (e.g., form **PTO/AIA/01**). For information about an inventor's oath or declaration for an application filed before September 16, 2012 (e.g., form **PTO/SB/01**), see MPEP 602.01(b).
- ☒ This request is being filed after the first Office action on the merits has been given or mailed (see 37 CFR 1.48(c) and 1.17(d)). Check one of the following:
- ☐ This request to correct or change the inventorship is due solely to the cancellation of claims in the application.
- OR
- ☒ The fee set forth in 37 CFR 1.17(d) is due (in addition to the fee set forth in 37 CFR 1.17(i)). \$ **640.00**

[Page 1 of 2]

This collection of information is required by 37 CFR 1.48. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN
INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION
(37 CFR 1.48)**

- ☐ 2. This request is to correct or update the name of the inventor or a joint inventor, or the order of names of joint inventors, in a **nonprovisional** application (**under 37 CFR 1.48(f)**) and includes:
- ☐ An application data sheet in accordance with 37 CFR 1.76(c) identifying the complete inventive entity, including the corrected or updated name of the inventor, or the new order of names shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the MPEP 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

☐ The processing fee set forth in 37 CFR 1.17(i). \$ _____

For a provisional application:

- ☐ This request is to change or correct the inventorship, or correct or update the name of the inventor or a joint inventor, in a **provisional** application (**under 37 CFR 1.48(d)**) and includes:
- ☐ **Attached hereto** is a document that is signed by a party set forth in 37 CFR 1.33(b) and identifies each inventor by his or her legal name, in the preferred order. Note: the document may be an application data sheet in accordance with 37 CFR 1.76(c) that identifies the changes with markings (underlining for insertions, strikethrough for deletions).
- ☐ The processing fee set forth in 37 CFR 1.17(q). \$ _____

Fee Payment Information:

- ☐ Applicant asserts small entity status. See 37 CFR 1.27.
- ☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously
- ☐ A check in the amount of the fee is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 03-1952.
- ☒ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ Applicant* ☒ attorney or agent of record ☐ attorney or agent acting under 37 CFR 1.34
Registration number 51,934 Registration number _____

Signature /Christine Lekutis/Typed or printed name Christine LekutisDate April 30, 2024

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. *Juristic entities must be represented by a patent practitioner (See 37 CFR 1.31, applicable to any paper filed on or after September 16, 2012 that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below**.

☐ ** Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	14639-20668.01
		Application Number	<u>18/486,053</u>
Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES		
<p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p>			

Secrecy Order 37 CFR 5.2:

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--------------------------	---

Inventor Information:

Inventor 1					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Ryan	Patrick	OWEN			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Millbrae	State/Province	CA	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		c/o Genentech, Inc.				
Address 2		1 DNA Way, MS49				
City	South San Francisco		State/Province	CA		
Postal Code	94080-4990		Country	US		
Inventor 2					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Ahmar		IQBAL			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	San Bruno	State/Province	CA	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		c/o Genentech, Inc.				
Address 2		1 DNA Way, MS49				
City	South San Francisco		State/Province	CA		
Postal Code	94080-4990		Country	US		
Inventor 3					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Robert	A.	WOOD			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	14639-20668.01		
		Application Number	18/486,053		
Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES				
City	Lutherville	State/Province	MD	Country of Residence ⁱ	US
Mailing Address of Inventor:					
Address 1	c/o Johns Hopkins University				
Address 2	3400 North Charles Street				
City	Baltimore	State/Province	MD		
Postal Code	21218-2683	Country ⁱ	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence Information of this application.			
Customer Number	25226		
Email Address	PatentDocket@mofo.com	<input type="button" value="Add Email"/>	<input type="button" value="Remove Email"/>

Application Information:

Title of the Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES		
Attorney Docket Number	14639-20668.01	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	2	Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country ⁱ

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	14639-20668.01
		Application Number	<u>18/486,053</u>
Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES		

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	25226		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78. When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	PCT/US2023/070639	2023-07-20
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2023/070639	Claims benefit of provisional	63/512,051	2023-07-05
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	14639-20668.01
		Application Number	<u>18/486,053</u>
Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES		

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	<div>Removeⁱ</div> Access Code ⁱ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013. NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	14639-20668.01
		Application Number	<u>18/486,053</u>
Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	14639-20668.01
		Application Number	<u>18/486,053</u>
Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.			
Applicant 1			
<p>If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.</p> <div style="text-align: right; margin-top: 10px;">Clear</div>			
☒ Assignee		☐ Legal Representative under 35 U.S.C. 117	
☐ Person to whom the inventor is obligated to assign.		☐ Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
Name of the Deceased or Legally Incapacitated Inventor: 			
If the Applicant is an Organization check here. ☒			
Organization Name		Genentech, Inc.	
Mailing Address Information For Applicant:			
Address 1		1 DNA Way	
Address 2			
City		South San Francisco	State/Province
Country		US	Postal Code
Phone Number		Fax Number	94080-4990
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	14639-20668.01
		Application Number	<u>18/486,053</u>
Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES		

Assignee 1			
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
If the Assignee or Non-Applicant Assignee is an Organization check here. ☒			
Organization Name	Genentech, Inc.		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	1 DNA Way		
Address 2			
City	South San Francisco	State/Province	CA
Country ⁱ	US	Postal Code	94080-4990
Phone Number		Fax Number	
Email Address			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Christine Lekutis/		Date (YYYY-MM-DD)	2024-04-30	
First Name	Christine	Last Name	Lekutis	Registration Number	51,934
Additional Signature may be generated within this form by selecting the Add button.					

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	14639-20668.01
		Application Number	<u>18/486,053</u>
Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES		

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)****Title of
Invention****ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES**

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

☒United States application or PCT international application number 18/486,053filed on October 12, 2023

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001
by fine or imprisonment of not more than five (5) years, or both.**WARNING:**

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTORInventor: Ahmar IqbalDate (Optional): 15-Apr-2024 | 12:34 PDTSignature: Ahmar Iqbal

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0032. Public burden for this form is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.** If filing this completed form by mail, send to: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention	ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES
<p>As the below named inventor, I hereby declare that:</p> <p>This declaration is directed to: ☐ The attached application, or</p> <p style="margin-left: 150px;">☒ United States application or PCT international application number <u>18/486,053</u></p> <p style="margin-left: 150px;">filed on <u>10/12/2023</u></p> <p>The above-identified application was made or authorized to be made by me.</p> <p>I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.</p> <p>I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.</p> <p style="text-align: center;">WARNING:</p> <p>Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.</p>	
<p>LEGAL NAME OF INVENTOR</p> <p>Inventor: <u>Robert A. Wood</u> Date (Optional) <u>4/1/24</u></p> <p>Signature: <u>Robert A. Wood</u> <u>Robert A. Wood</u></p>	
<p><small>Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.</small></p>	

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

AMENDMENTS TO THE DRAWINGS

The attached replacement sheet of drawings includes changes to previous Sheet 2/2. The replacement sheet, which includes FIG. 2, replaces the original sheet including FIG. 2. In brief, two errors in the Baseline IgE of the first column have been corrected. Specifically, “>30-100” has been replaced by “ $\geq$ 30-100” and “>1500-1800” has been replaced by “>1500-1850.”

Attachment: One (1) Replacement Sheet

REMARKS

Claims 95-124 were pending in the present application. By virtue of this amendment, Claims 95-98, 100, 101, 103, 108, 110, 112, 117, 121 and 122 have been amended, Claims 99, 102, 104-107, 109, 111, 113-116, 118-120 and 123 have been canceled, and new Claims 125-139 have been added, as provided in the listing of claims. Accordingly, upon entry of this amendment, Claims 95-98, 100, 101, 103, 108, 110, 112, 117, 121, 122 and 124-139 are pending, amounting to a total of 4 independent claims and 29 total claims.

Claims 95, 97, 100 and 117 have been amended to recite “equal to or greater than 30 IU/ml” for the sake of consistency. Support for this amendment can be found, for example, in paragraph [0062] of the Specification, original Claims 21, 23, 26, 65, 69, 75, 78 and 80, as well as Claim 116 as previously presented.

Claims 96, 97, 98, 100, 112, 117 and 121 have been amended to recite “wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.” Support for this amendment can be found, for example, in paragraph [0063] of the Specification, original Claim 48, as well as Claims 102, 113, 118 and 122 as previously presented.

Claim 108 has been amended to recite “wherein treating comprises reducing an allergic reaction following accidental exposure of the subject to the food allergen.” Support for this amendment can be found, for example, in paragraphs [0009] and [0021] of the Specification, as well as Claims 108 and 109 as previously presented.

Claim 110 has been amended to recite “wherein treating comprises reducing a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.” Support for this amendment can be found, for example, in paragraph [0040] of the Specification, original Claim 42, as well as Claims 108 and 110 as previously presented.

Claims 112 and 117 have both been amended to depend upon independent Claim 95, instead of Claims 111 and 116, which have been canceled. Accordingly, elements from Claims 111 and 116 have been introduced into Claims 112 and 117.

The preamble of Claim 121 has been shortened in view of total serum IgE level limitations being presented in the body of the claim.

Claim 122 has been amended to recite “wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.” This amendment was made as a consequence of the amendment of Claim 121, upon which it depends.

New Claim 127 is an independent claim, which encompasses the doses of omalizumab and the dosing frequency of the ≥ 10 -12 and > 12 -15 body weight columns of the omalizumab dosing table of FIG. 2.

New Claims 128-134 ultimately depend upon new Claim 127. Support for these claims can be found, for example, in Claims 101, 103 and 105-110 as previously presented.

New Claim 135 is an independent version of Claim 99, now canceled. As such, Claim 135 encompasses the doses of omalizumab and the dosing frequency of the ≥ 10 -12 body weight column of the omalizumab dosing table of FIG. 2.

New Claims 136-139 depend upon Claim 135, and correspond to Claims 101, 103 and 108-110 as previously presented.

Other minor amendments are self explanatory. Further support for the amendments and new claims can be found throughout the application as filed, and the claims as previously presented. Thus, no new matter has been added.

With respect to any claim amendments or cancellations, Applicant has neither dedicated to the public nor abandoned any unclaimed subject matter. Applicant expressly reserves the right to pursue protection for any presently excluded subject matter or claims in one or more future continuing application(s).

Amendment of the Specification

The Specification has been amended to include a Statement Regarding Federally Sponsored Research or Development and applicable numbers of awards made by the National Institutes of Health.

In addition, the Specification has been amended to correct clerical errors in paragraph [0029]. Specifically, the Specification has been amended to recite the “amino acid sequences of the heavy chain variable region (VH) and the light chain variable region (VL) of omalizumab are ... set forth herein as SEQ ID NO:3 and SEQ ID NO:4, respectively” and to recite the “amino acid sequences of the full length heavy chain and the full length light chain of omalizumab are ... are set forth herein as SEQ ID NO:1 and SEQ ID NO:2, respectively.” The sequences disclosed on page 61 of the application as filed, along with the electronic sequence listing, clearly show that the shorter heavy and light chain variable region sequences are set forth as SEQ ID NO:3 and SEQ ID NO:4, while the longer heavy and light chain sequences are set forth as SEQ ID NO:1 and SEQ ID NO:2. Thus, no new matter has been introduced.

Amendment of the Drawings

In amended FIG. 2 of replacement Sheet 2/2, two errors in the Baseline IgE of the first column have been corrected. Specifically, the third row has been amended to read “ ≥ 30 -100” and the seventeenth row has been amended to read “ > 1500 -1850.” Support for these amendments can be found in, but is not limited to, original Sheet 2/2 including FIG. 2 of the two priority applications, PCT/US2023/070639, filed internationally on July 20, 2023, and U.S. Provisional Application No. 63/512,051, filed July 5, 2023. Contents of both of the priority applications were incorporated by reference by virtue of a Preliminary Amendment filed with the instant application on October 12, 2023. As such, no new matter has been introduced.

Substance of Interview

This is in reply to the Interview Summary dated April 10, 2024 (Paper No. 20240405). Applicant thanks Examiner Szperka for his participation in a telephone interview on April 5, 2024, with Christine Lekutis and Jie Zhou of Morrison & Foerster LLP. During the

interview, the rejections of the pending Office Action and responses for overcoming the rejections were discussed.

Correction of Inventorship

Filed herewith is a Request for Correction of Inventorship, to add Ahmar Iqbal and Robert A. Wood as Inventors. Declarations executed by Inventors Iqbal and Wood are also filed herewith, along with applicable fees.

Claim Rejections - 35 U.S.C. § 102

1. Claims 95-124 were rejected under 35 U.S.C. § 102(a)(1) as allegedly anticipated by Wood et al., J Allergy Clin Immunol Glob, 1(4)225-232, July 21, 2022 (hereinafter the “Wood Publication”). In lodging this rejection, the Examiner specifically referred to Supplemental Figure 1 of the Wood Publication, which corresponds to the omalizumab dosing table of FIG. 2 of the instant application (Office Action, page 3).

Applicant respectfully traverses this rejection and associated remarks. Applicant notes that the July 21, 2022, disclosure of the Wood Publication, which lists Inventors Wood and Iqbal as co-authors, is within one year of the filing dates of the two priority applications (PCT/US2023/070639, filed internationally on **July 20, 2023**, and U.S. Provisional Application No. 63/512,051, filed **July 5, 2023**). In addition, a Declaration of Inventor Iqbal under 37 C.F.R. § 1.130(a) is filed herewith (**Exhibit A**) as evidence that the subject matter of the pending claims as disclosed in the Wood Publication is attributable to the inventors. As such the disclosure of the Wood Publication as it pertains to the pending claims should be disqualified as prior art under the 35 U.S.C. § 102(b)(1)(A) exception.

Since the Wood Publication is not prior art, Applicant respectfully requests that this rejection be withdrawn.

2. Claims 95-124 are rejected under 35 U.S.C. § 102(a)(1) as allegedly anticipated by CONSORTIUM FOR FOOD ALLERGY RESEARCH (“Protocol CoFAR-11 Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults OUtMATCH,” Version 6.0 dated June 13, 2022), NPL Reference 37 of the IDS filed on

December 8, 2023 (hereinafter the “Protocol Document”). In lodging this rejection, the Examiner specifically referred to Appendix 2 of the Protocol Document, which corresponds to the omalizumab dosing table of FIG. 2 of the instant application (Office Action, page 5).

Applicant respectfully traverses this rejection and associated remarks. Although the Protocol Document lists an earlier date, it was not disclosed to the public before it was published online by the National Institute of Allergy and Infectious Diseases (NIAID) on February 23, 2023, as shown in the screenshot of the NIAID website of NPL Reference 38 of the IDS filed on December 8, 2023. As such, the disclosure of the Protocol Document, which lists Inventor Wood, is within one year of the filing dates of the two priority applications (PCT/US2023/070639, filed internationally on **July 20, 2023**, and U.S. Provisional Application No. 63/512,051, filed **July 5, 2023**). The Declaration of Inventor Iqbal under 37 C.F.R. § 1.130(a) described above and filed herewith (**Exhibit A**) also serves as evidence that the subject matter of the pending claims as disclosed in the Protocol Document is attributable to the inventors. As such the disclosure of the Protocol Document as it pertains to the pending claims should be disqualified as prior art under the 35 U.S.C. § 102(b)(1)(A) exception.

Since the Protocol Document is not prior art, Applicant respectfully requests that this rejection be withdrawn.

Double Patenting

1. Claims 95-124 are rejected on the ground of nonstatutory double patenting as allegedly unpatentable over Claims 1-24 of U.S. Patent No. 10,034,940 of Liu et al. (“’940 Patent”) in view of the Wood Publication and/or the Protocol Document (“Secondary Reference(s)”). In lodging this rejection, the Examiner acknowledges that the claims of the ’940 Patent differ from the claims of the instant application in that “neither the mass of omalizumab administered nor the time interval between administrations is recited” and therefore relies on the Secondary Reference(s) to remedy these and other deficiencies (Office Action, page 7).

Applicant respectfully traverses this rejection and notes that a “secondary reference used to support an obviousness analysis for a nonstatutory double patenting rejection must be prior art under 35 U.S.C. § 102” (MPEP § 804(II)(B)(3)). The pending claims are patentably distinct from

Claims 1-24 of the '940 Patent, and as detailed above, the Secondary Reference(s) are not prior art.

Given that Claims 1-24 of the '940 Patent, in the absence of the Secondary Reference(s), do not render the pending claims unpatentable, Applicant respectfully requests that this rejection be withdrawn.

2. Claims 95-124 are rejected on the ground of nonstatutory double patenting as allegedly unpatentable over Claims 1-14 of U.S. Patent No. 8,961,964 ("964 Patent") in view of the Wood Publication and/or the Protocol Document ("Secondary Reference(s)"). In lodging this rejection, the Examiner acknowledges that the claims of the '964 Patent differ from the claims of the instant application in that "no methods of treatment, for food allergy or any other IgE-mediated disorder, are recited" and therefore relies on the Secondary Reference(s) to remedy these and other deficiencies (Office Action, page 10).

Applicant respectfully traverses this rejection and notes that a "secondary reference used to support an obviousness analysis for a nonstatutory double patenting rejection must be prior art under 35 U.S.C. § 102" (MPEP § 804(II)(B)(3)). The pending claims are patentably distinct from Claims 1-14 of the '964 Patent, and as detailed above, the Secondary Reference(s) are not prior art.

Given that Claims 1-14 of the '964 Patent, in the absence of the Secondary Reference(s), do not render the pending claims unpatentable, Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **14639-20668.01**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 30, 2024

Respectfully submitted,

By /Christine Lekutis/

Christine Lekutis

Registration No.: 51,934

MORRISON & FOERSTER LLP

425 Market Street

San Francisco, CA 94105-2482

+1 (415) 268-7060

Attachments

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ryan Patrick OWEN

Application No.: 18/486,053

Confirmation No.: 7842

Filed: October 12, 2023

Art Unit: 1641

For: ANTI-IGE ANTIBODY THERAPY FOR
MULTIPLE FOOD ALLERGIES

Examiner: M. E. Szperka

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Applicant has become aware that the dates of the clinicaltrials.gov references listed in the initial Information Disclosure Statement (IDS) filed on December 8, 2023, were not shown consistently, such that several of the dates listed correspond to submission rather than posting dates. Also, the date of another reference was only listed as its later online publication date, rather than its original publication date. In order to remedy these inadvertent errors, a Replacement Form PTO/SB/08a is filed herewith, which includes corrections to the dates of the non-patent literature (NPL) References 19-36 and 49 of the initial IDS. Citations of other references on the initial IDS have not been changed in the Replacement Form PTO/SB/08a. Copies of the foreign documents and NPL References 1-75 listed on the Replacement Form PTO/SB/08a were previously submitted with the IDS filed on December 8, 2023.

In addition, a supplemental IDS is being filed to submit further references for consideration in the instant application. Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicant submits for consideration in the above-identified application the documents listed on the attached Supplemental Form PTO/SB/08a. Copies of U.S. Patent Publications and Patents are not submitted herewith pursuant to 37 C.F.R. § 1.98(a)(2)(ii). Copies of the foreign documents and

sf-5740956

non-patent literature listed on the Supplemental Form PTO/SB/08a are submitted herewith. The Examiner is requested to make these documents of record.

Applicant would appreciate the Examiner initialing and returning the Replacement and Supplemental Forms PTO/SB/08a, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing **14639-20668.01**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 30, 2024

Respectfully submitted,

By /Christine Lekutis/
Christine Lekutis

Registration No.: 51,934
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
+1 (415) 268-7060

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18486053
	Filing Date		2023-10-12
	First Named Inventor	Ryan Patrick OWEN	
	Art Unit	1641	
	Examiner Name	M. E. Szperka	
	Attorney Docket Number	14639-20668.01	

U.S.PATENTS Remove						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8961964	B2	2015-02-24	Liu et al.	
	2	10166293	B2	2019-01-01	Liu et al.	
	3	10370456	B2	2019-08-06	Winter	
	4	11767370	B2	2023-09-26	Winter	
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U.S.PATENT APPLICATION PUBLICATIONS Remove						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050031609	A1	2005-02-10	Hultsch et al.	
	2	20080206237	A1	2008-08-28	Owen et al.	

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Attorney Docket Number		14639-20668.01		

	3	20210095050	A1	2021-04-01	Winter	
	4	20230227582	A1	2023-07-20	Ivan et al.	

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button.

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	ALBA JORDA, P. et al. (June 5, 2019). "Omalizumab in Spontaneous Food Tolerance in Adult Patients," Allergy, Abstract No. OA0198, 1 page.	☐
	2	ARM, J.P. et al. (November 2014). "Pharmacokinetics, Pharmacodynamics and Safety of QGE031 (Ilgelizumab), A Novel High-Affinity Anti-IgE Antibody, in Atopic Subjects," Clin Exp Allergy, 44:1371-1385, with supplementary materials, 36 pages.	☐
	3	AZZANO, P. et al., (January 2021, e-pub. September 24, 2020). "Determinants of Omalizumab Dose-Related Efficacy in Oral Immunotherapy: Evidence from a Cohort of 181 Patients," J Allergy Clin Immunol, 147(1):233-243.	☐
	4	BARNI, S. et al. (March 4, 2020). "Immunoglobulin E (IgE)-Mediated Food Allergy in Children: Epidemiology, Pathogenesis, Diagnosis, Prevention, and Management," Medicina, 56:111, 16 pages.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18486053
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	Examiner Name	M. E. Szperka	
	Attorney Docket Number	14639-20668.01	

5	BOZOGHLANIAN, V. et al. (2017). "Efficacy of Omalizumab in Reducing Food Allergy," J Allergy Clin Immunol, 139(2): AB135, Abstract No. 432, 1 page.	☐
6	BURK, C.M. et al. (2017, e-pub. December 22, 2016). "Eosinophilic Esophagitis During Peanut Oral Immunotherapy with Omalizumab," J Allergy Clin Immunol Pract, 5(2):498-501.	☐
7	CHANG, T.W. et al. (2012). "The Pharmacological Mechanisms of Omalizumab in Patients with Very High IgE Levels – Clues from Studies on Atopic Dermatitis," Dermatologica Sinica 30:147-153.	☐
8	CHASE, N. et al. (November 10-14, 2022). "Improvements in Select Patient-Reported Outcomes are Similar Across Different Omalizumab Dosing Regimens," Poster presented at the American College of Allergy, Asthma & Immunology (ACAAI) 2022 Annual Scientific Meeting, Louisville, KY, 1 page.	☐
9	CHINUKI, Y. et al. (2020, e-pub. November 18, 2019). "In Vitro Basophil Activation is Reduced by Short-Term Omalizumab Treatment in Hydrolyzed Wheat Protein Allergy," Allergology International 69:284-286.	☐
10		☐
11	GAUVREAU, G.M. et al. (October 2016, e-pub. April 7, 2016). "Efficacy and Safety of Multiple Doses of QGE031 (ligelizumab) Versus Omalizumab and Placebo in Inhibiting Allergen-Induced Early Asthmatic Responses," J Allergy Clin Immunol, 138(4):1051-1059.	☐
12	GENENTECH PRESS RELEASE (August 12, 2018). "FDA Grants Breakthrough Therapy Designation for Xolair (Omalizumab) for Food Allergies," 3 pages.	☐
13	GERNEZ, Y. et al. (2011, e-pub. October 25, 2010). "Basophil CD203c Levels are Increased at Baseline and Can be Used to Monitor Omalizumab Treatment in Subjects with Nut Allergy," Int Arch Allergy Immunol, 154:318-327.	☐
14	HUTYROVÁ, B. et al. (2018, e-pub. July 19, 2018). "The Effect of Omalizumab Treatment on Severe Allergic Asthma and Allergic Comorbidities: Real-Life Experience from the Czech Anti-IgE Registry," Adv Dermatol Allergol. 35(5): 510-515.	☐
15	IBÁÑEZ-SANDÍN, M.D. et al. (2021). "Oral Immunotherapy in Severe Cow's Milk Allergic Patients Treated with Omalizumab: Real Life Survey from a Spanish Registry," Pediatr Allergy Immunol, 32:1287-1295.	☐

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	Attorney Docket Number	14639-20668.01	

16	INCORVAIA, C. et al. (2008). "Current and Future Applications of the Anti-IgE Antibody Omalizumab," <i>Biologics: Targets & Therapy</i> 2(1):67-73.	☐
17	JOHANSSON, S.G.O. et al. (2009). "The Size of the Disease Relevant IgE Antibody Fraction in Relation to 'Total-IgE' Predicts the Efficacy of Anti-IgE (Xolair) Treatment," <i>Allergy</i> , 64:1472-1477.	☐
18	KOPP, M.V. (2011). "Omalizumab: Anti-IgE Therapy in Allergy," <i>Curr Allergy Asthma Rep</i> , 11:101-106.	☐
19	LAFUENTE, I. et al. (2015). "Possible Recurrence of Symptoms After Discontinuation of Omalizumab in Anti-IgE-Assisted Desensitization to Egg," <i>Pediatric Pulmonology and Allergy</i> 25:714-728.	☐
20	LEE, E.Y. et al. (2021). "Delayed Hypersensitivity Reactions to Multiple Aromatase Inhibitors Followed by Successful Desensitization to Letrozole," <i>Ann Allergy Asthma Immunol</i> , 127:378-397.	☐
21	LEUNG, D.Y.M. et al. (March 13, 2003). "Effect of Anti-IgE Therapy in Patients with Peanut Allergy," <i>The New England Journal of Medicine</i> 348:986-993.	☐
22	LOWE, P.J. et al. (2016). "Integrated Quantitation of Biotherapeutic Drug–Target Binding, Biomarkers, And Clinical Response To Support Rational Dose Regimen Selection," Chapter 13 In <i>ADME and Translational Pharmacokinetics/ Pharmacodynamics of Therapeutic Proteins: Applications in Drug Discovery and Development</i> , H. Zhou and F-P Theil (eds). John Wiley & Sons, Inc., pp. 175-195.	☐
23	MACGLASHAN, D.W. et al. (November 2012). "Suppression of the Basophil Response to Allergen During Treatment with Omalizumab is Dependent on 2 Competing Factors," <i>J Allergy Clin Immunol</i> , 130(5):1130-1135, plus supplemental figures, 11 pages.	☐
24	MARI, A. et al. (2017). "Omalizumab Treatment for Severe Food Allergy Caused by Lipid Transfer Protein: A Preliminary Case Series," <i>Allergy</i> , 72(Suppl. 103):338, Abstract No. 0501, 1 page.	☐
25	MCGOWAN, E.C. et al. (November 2013). "Prevalence of Self-Reported Food Allergy in the National Health and Nutrition Examination Survey (NHANES) 2007 – 2010," <i>J Allergy Clin Immunol</i> , 132(5):1-6, 6 pages.	☐
26	MENDONÇA, R.B. et al. (2012, e-pub. July 12, 2011). "Open Oral Food Challenge in the Confirmation of Cow's Milk Allergy Mediated by Immunoglobulin E," <i>Allergologia et Immunopathologia</i> 40(1):25-30.	☐

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27	NILSSON, C. et al. (2014). "Successful Management of Severe Cow's Milk Allergy with Omalizumab Treatment and CD-sens Monitoring," Asia Pacifica Allergy, 4:257-260.	☐
28	PELOCHE, M.P. et al. (August 12, 2011). "Severe Food Allergy in Children. Omalizumab as an Alternative Treatment to Elimination Diet," Clinical and Translational Allergy 1(Suppl. 1):P55, 1 page.	☐
29	RAFI, A. et al. (January/February 2010). "Effects of Omalizumab in Patients with Food Allergy," Allergy Asthma Proc, 31(1):76-83.	☐
30	SALARI, F. et al. (2022). "The Effectiveness of Oral Immunotherapy in Patients with Sesame Anaphylaxis Using Omalizumab," Clinical Medicine & Research 20(3):125-132.	☐
31	SAVAGE, J. et al. (2016). "The Natural History of Food Allergy," J Allergy Clin Immunol Pract, 4(2):196-203.	☐
32	WOOD, R.A. (April 2016). "Food Allergen Immunotherapy: Current Status and Prospects for the Future," J Allergy Clin Immunol, 137:973-982.	☐
33	WOOD, R.A. (2017). "Oral Immunotherapy for Food Allergy," J Investig Allergol Clin Immunol, 27(3):151-159.	☐
34	WOOD, R.A. et al. (March 7, 2024, e-pub. February 25, 2024). "Omalizumab for the Treatment of Multiple Food Allergies," The New England Journal of Medicine, 390(10):889-899.	☐
35	XOLAIR® (2015). "Summary of Product Characteristics," European Public Assessment Report. 259 pages.	☐
36	XOLAIR® (July 21, 2015). "Australian Product Information for Omalizumab," Australian Public Assessment Report. 33 pages.	☐
37	XOLAIR® (March 22, 2023). "Summary of Product Characteristics," European Public Assessment Report. 179 pages.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18486053
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	Art Unit	1641	
	Examiner Name	M. E. Szperka	
	Attorney Docket Number	14639-20668.01	

	38	XOLAIR® (November 25, 2005). "Scientific Discussion," European Public Assessment Report. 34 pages.	☐
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EXAMINER SIGNATURE			
Examiner Signature			Date Considered
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
<small> ¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached. </small>			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18486053
	Filing Date		2023-10-12
	First Named Inventor	Ryan Patrick OWEN	
	Art Unit	1641	
	Examiner Name	M. E. Szperka	
	Attorney Docket Number	14639-20668.01	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Christine Lekutis/	Date (YYYY-MM-DD)	2024-04-30
Name/Print	Christine Lekutis	Registration Number	51934

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/486,053	10/12/2023	Ryan Patrick OWEN	14639-20668.01

25226
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

CONFIRMATION NO. 7842

**37 CFR 1.48 ACKNOWLEDGEMENT
LETTER**



OC000000072032129

Date Mailed: 05/02/2024

NOTICE OF ACCEPTANCE OF REQUEST UNDER 37 CFR 1.48(a)

This is in response to the applicant's request under 37 CFR 1.48(a) submitted on 04/30/2024.

The request under 37 CFR 1.48(a) to correct the inventorship, to correct or update the name of an inventor, or to correct the order of names of joint inventors is accepted.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/sstephanos/



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

25226 7590 05/22/2024
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/22/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/486,053	10/12/2023	Ryan Patrick OWEN	14639-20668.01	7842

TITLE OF INVENTION: ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	08/22/2024

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

25226 7590 05/22/2024
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

_____ (Typed or printed name)
_____ (Signature)
_____ (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/486,053	10/12/2023	Ryan Patrick OWEN	14639-20668.01	7842

TITLE OF INVENTION: ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	08/22/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
SZPERKA, MICHAEL EDWARD	1641	424-131100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via the USPTO patent electronic filing system ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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755 PAGE MILL RD			ART UNIT	
PALO ALTO, CA 94304-1018			PAPER NUMBER	
			1641	
DATE MAILED: 05/22/2024				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).

<https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf>

Routine uses of the information in this record may include disclosure to:

- 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
- 2) a federal, state, local, or international agency, in response to its request;
- 3) a contractor of the USPTO having need for the information in order to perform a contract;
- 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
- 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
- 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
- 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
- 8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
- 9) the Office of Personnel Management (OPM) for personnel research purposes; and
- 10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 18/486,053	Applicant(s) OWEN et al.	
	Examiner Michael Szperka	Art Unit 1641	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 30 April 2024.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are See Continuation Sheet. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____.	7. ☐ Other ____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date ____.	

/MICHAEL SZPERKA/ Primary Examiner, Art Unit 1641	
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Continuation of 3. The allowed claim(s) is/are: 95-98,100-101,103,108,110,112,117,121-122 and 124-139

DETAILED ACTION

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Applicant's response and amendments received April 30, 2024 are acknowledged.

Claims 1-94, 99, 102, 104-107, 109, 111, 113-116, 118-120, and 123 have been canceled.

Claims 95-98, 100, 101, 103, 108, 110, 112, 117, 121, and 122 have been amended.

Claims 125-139 have been added.

Claims 95-98, 100, 101, 103, 108, 110, 112, 117, 121, 122, and 124-139 are pending in the instant application.

Information Disclosure Statement

2. The IDS form received 4/30/2024 are acknowledged and the references therein have been considered.

Drawings

1. The corrected version of Figure 2 received 4/30/2024 is acknowledged. Note that it appears to be identical to Figure 2 as presented in provisional application 63/512,051 to which the instant application claims priority.

Claim Rejections - 35 USC § 102

3. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will

not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

(a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

4. The rejection of claims 95-124 under 35 U.S.C. 102(a)(1) as being anticipated by Wood et al. has been withdrawn in view of applicant's response received April 30, 2024.

Specifically, applicant has corrected inventorship of the instant application and has supplied a declaration under 37 CFR 1.130(a) by inventor Iqbal clearly indicating that the Wood reference falls within the 1 year grace period and is disqualified as prior art as it is not work done by another.

5. The rejection of claims 95-124 under 35 U.S.C. 102(a)(1) as being anticipated by CONSORTIUM FOR FOOD ALLERGY RESEARCH ("Protocol CoOFAR-11 Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults OUtMATCH", Version 6.0 dated June 13, 2022, supplied as reference 37 on the 12/8/2023 IDS, hereafter "CoOFAR") has been withdrawn in view of applicant's evidence that a) the actual date upon which the document in question entered the public domain is February 23, 2023 when it was first published online by NIAID and b) that this protocol is attributable to the authors and does not qualify as prior art as set forth in the declaration of inventor Iqbal under 37 CFR 1.130 received 4/30/2024. Note that the correct date of public availability falls with the grace period exception as set forth in 35 USC 102(b)(1)(A).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

7. The rejection of claims 95-124 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 10,034,940 in view of Wood et al. and/or CONSORTIUM FOR FOOD ALLERGY RESEARCH ("Protocol CoOFAR-11 Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults OUTMATCH", Version 6.0 dated June 13, 2022, supplied as reference 37 on the 12/8/2023 IDS, hereafter "CoOFAR") has been withdrawn in view of applicant's response received April 30, 2024.

Specifically, neither the Wood nor the CoOFAR papers qualify as prior art as was discussed earlier in this office action. As such, the rejection has been withdrawn.

8. The rejection of claims 95-124 on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 8,961,964 in view of Wood et al. and/or CONSORTIUM FOR FOOD ALLERGY RESEARCH ("Protocol CoOFAR-11 Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults OUTMATCH", Version 6.0 dated June 13, 2022, supplied as reference 37 on the 12/8/2023 IDS, hereafter "CoOFAR") has been withdrawn in view of applicant's response received April 30, 2024.

Specifically, neither the Wood nor the CoOFAR papers qualify as prior art as was discussed earlier in this office action. As such, the rejection has been withdrawn.

9. Claims 95-98, 100, 101, 103, 108, 110, 112, 117, 121, 122, and 124-139 are allowable.

Applicant has claimed methods of treating food allergies by administering omalizumab. Administering omalizumab to treat food allergies, such as peanut allergies, was known in the prior art. See for example U.S. Patent No. 10,034,940. However, the instant claims recite a relationship between the mass of omalizumab administered to the patient, the body mass of the patient, the disease severity as measured by total serum IgE, and the time interval between administrations that was not disclosed in the prior art, nor do the instant recited limitations appear to be obvious

variations of prior art dosing protocols. Indeed, the instant recited patient masses are smaller than those found in dosing charts such as those of the FDA prescribing label for XOLAIR (aka omalizumab, see reference 43 on the 4/30/24 IDS) and thus data on the pediatric patients encompassed by the claimed methods (which even though not recited as being "pediatric," humans of the recited body masses realistically can only be young children) was not present in the prior art. Note that the instant claimed methods provide clinical benefits to children within the recited body mass ranges as demonstrated by the clinical data disclosed in the instant specification. See Example 1, most particularly pages 55-59 and Tables 1.4 and 1.5). Artisans would reasonably have no trouble whatsoever following the instant recited dosing protocol, and administration of antibodies, including omalizumab, is quite routine in the medical arts as again evidenced by the '940 patent. Therefore the instant claimed inventions have been found to be allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached Monday-Friday 8:30-5:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For

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additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka
Primary Examiner
Art Unit 1641

/MICHAEL SZPERKA/
Primary Examiner, Art Unit 1641



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18/486,053	07/09/2024	12030959	14639-20668.01	7842

25226 7590 06/19/2024
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at <https://patentcenter.uspto.gov/>. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at <https://certifiedcopycenter.uspto.gov/index.html>. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Center (<https://patentcenter.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PATENT CENTER site <https://patentcenter.uspto.gov> for additional inventors):

Ryan Patrick OWEN, Millbrae, CA;
Ahmar IQBAL, San Bruno, CA;
Robert A. WOOD, Lutherville, MD;

APPLICANT(s) (Please see PATENT CENTER site <https://patentcenter.uspto.gov> for additional applicants):

Genentech, Inc., South San Francisco, CA;

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of: Ryan Patrick OWEN et al.

Patent No.: 12,030,959

Issued On: July 9, 2024

For: ANTI-IGE ANTIBODY THERAPY FOR
MULTIPLE FOOD ALLERGIES

**REQUEST FOR CERTIFICATE OF CORRECTION
PURSUANT TO 37 C.F.R. § 1.323**

Attention: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Upon reviewing the above-identified patent, Patentee respectfully requests that the Assignee of the above-captioned patent be corrected under 37 CFR 3.81(b) to add the following Assignee:

Under the Assignee section on the face page:

At line number 73, before Genentech, Inc., South San Francisco, CA (US), please add --
Novartis AG, Basel (CH)--.

The assignment, noting the proper Assignees, Genentech, Inc. and Novartis AG, was recorded on June 20, 2024, *before* issuance of the patent, on Reel 067807/Frame 0298, as required by 37 CFR § 3.11. This Request is submitted with the fees set forth in 37 C.F.R. § 1.20(a) and 37 CFR § 1.17(i)(1).

sf-6571977

Patent No.: 12,030,959

Docket No.: 14639-20668.01

Transmitted herewith is a proposed Certificate of Correction effecting such amendment. Patentee respectfully solicits the granting of the requested Certificate of Correction.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Patentee petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **14639-20668.01**.

Dated: May 12, 2025

Respectfully submitted,

By /Jillian Pesin-Fulop/
Jillian Pesin-Fulop
Registration No.: 63,950
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
+1 (617) 648-4772



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

CERTIFICATE OF CORRECTION

APPLICATION #	PATENT #	RECEIPT DATE	ATTORNEY DOCKET #
18486053	12030959	05/12/2025	14639-20668.01

Title of Invention

ANTI-IGE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	12030959
CONFIRMATION #	7842	FILED BY	Carolina Herrera
PATENT CENTER #	70390166	AUTHORIZED BY	Jillian Pesin-Fulop
CUSTOMER #	25226	FILING DATE	10/12/2023
		FIRST NAMED INVENTOR	Ryan OWEN

Correction

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (73) Assignee, Please change "Genentech, Inc." to --Novartis AG; Genentech, Inc.--.

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

Page 1 of 1

PATENT NO. : 12,030,959

APPLICATION NO.: 18/486,053

ISSUE DATE : July 9, 2024

INVENTOR(S) : Ryan Patrick OWEN et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Under the Assignee section on the face page:

At line number 73, before Genentech, Inc., South San Francisco, CA (US), please add --Novartis AG, Basel (CH)--.

MAILING ADDRESS OF SENDER (Please do not use Customer Number below):

MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary, and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 12,030,959 B1
APPLICATION NO. : 18/486053
DATED : July 9, 2024
INVENTOR(S) : Ryan Patrick Owen et al.

Page 1 of 1

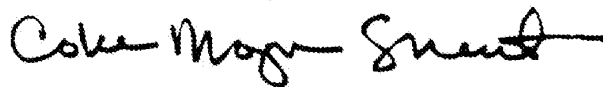
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Under the Assignee:

At item (73), before Genentech, Inc., South San Francisco, CA (US), please add --Novartis AG, Basel (CH)--.

Signed and Sealed this
Tenth Day of June, 2025

A handwritten signature in black ink, appearing to read "Coke Morgan Stewart", written in a cursive style.

Coke Morgan Stewart
Acting Director of the United States Patent and Trademark Office



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/486,053	10/12/2023	Ryan Patrick OWEN	14639-20668.01	7842
25226 7590 06/10/2025 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER SZPERKA, MICHAEL EDWARD	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 06/10/2025	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficePA@mofo.com
PatentDocket@mofo.com
pair_mofo@firsttofile.com



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	ISSUE DATE	PATENT NO.
18/486,053	10-Jun-2025	12030959

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

ELECTRONIC CERTIFICATE OF CORRECTION NOTIFICATION

Your electronic certificate of correction is now available, and can be accessed via Patent Center at <https://patentcenter.uspto.gov>.

The electronic certificate of correction is the official certificate of correction under 35 U.S.C. 254 or 255. For more information, please visit <https://www.uspto.gov/electronicgrants>.