

Sunday, Aug 12, 2018

FDA Grants Breakthrough Therapy Designation for Xolair (Omalizumab) for Food Allergies

There are currently no FDA-approved treatments that help prevent severe reactions due to food allergies

As many as 15 million Americans have food allergies – including approximately 6 million children – and the incidence is increasing

South San Francisco, CA -- August 12, 2018 --

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for Xolair® (omalizumab) for the prevention of severe allergic reactions following accidental exposure to one or more foods in people with allergies. Breakthrough Therapy Designation is designed to expedite the development and review of medicines intended to treat serious or life-threatening diseases, and to help ensure people have access to them through FDA approval as soon as possible. This is the 23rd Breakthrough Therapy Designation for Genentech's portfolio of medicines.

"Food allergies can have a significant impact on the lives of children and adults, and they are a growing public health concern for which there are currently no FDA-approved treatments," said Sandra Horning, M.D., chief medical officer and head of Global Product Development. "We are committed to helping address this high unmet medical need and look forward to working with leaders in the field to further develop Xolair as a potential medicine to help people with this condition that can be life-threatening."

Food allergies can be life-threatening, and result in an estimated 200,000 emergency room visits each year. Up to 8 percent of children and 4 percent of adults in the U.S. are affected by food allergies, and the incidence is increasing.

Breakthrough Therapy Designation was granted on the basis of data from seven clinical studies over the last decade assessing the efficacy and safety of Xolair against a range of food allergens including peanut, milk, egg and others. These studies of Xolair, as monotherapy or in combination with oral immunotherapy (OIT), were supported by Genentech and independent sponsors including the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Genentech and Novartis Pharmaceuticals Corporation are working closely with NIAID and the Consortium of Food Allergy Research (CoFAR) to initiate a potentially pivotal study evaluating the efficacy and safety of Xolair in multiple food allergies and will disclose details at a later date.

In the U.S., Genentech, Inc. and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair. Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. Novartis Pharmaceuticals Corporation is an affiliate of Novartis which provides innovative healthcare solutions that address the evolving needs of patients and societies.

About Xolair

Xolair for subcutaneous use is an injectable prescription medicine approved by the FDA to treat:

- Moderate to severe persistent asthma in patients six years of age or older whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if a patient has allergies to year-round allergens.
 - Chronic idiopathic urticaria (CIU; chronic hives without a known cause) in patients 12 years of age and older who continue to have hives that are not controlled by H1 antihistamine treatment.
- Xolair is not used to treat other allergic conditions, other forms of urticaria, acute bronchospasm or status asthmaticus.

Important Safety Information

The most important information patients should know about XOLAIR is that a severe allergic reaction called anaphylaxis can happen when a patient receives Xolair. The reaction can occur after the first dose, or after many doses. It may also occur right after a Xolair injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Patients must go to the nearest emergency room right away if they have any of these symptoms of an allergic reaction:

- wheezing, shortness of breath, cough, chest tightness or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety or feeling of "impending doom"
- flushing, itching, hives or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice or trouble swallowing

The patient's healthcare provider will monitor the patient closely for symptoms of an allergic reaction while they are receiving Xolair and for a period of time after the patient's injection. The patient's healthcare provider should talk to the patient about getting medical treatment if they have symptoms of an allergic reaction after leaving the healthcare provider's office or treatment center.

Patients must not receive Xolair if they are allergic to omalizumab or any of the ingredients in Xolair.

Before receiving Xolair, patients must tell their healthcare provider about all of their medical conditions, including if they:

- have any other allergies (such as food allergy or seasonal allergies)
- have sudden breathing problems (bronchospasm)
- have ever had a severe allergic reaction called anaphylaxis
- have or have had a parasitic infection
- have or have had cancer
- are pregnant or plan to become pregnant. It is not known if Xolair may harm a patient's unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Xolair passes into breast milk. Talk with your healthcare provider about the best way to feed your baby while you receive Xolair.

Patients must tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins or herbal supplements.

Receiving Xolair

- Xolair should be given by a healthcare provider, in a healthcare setting.
- Xolair is given in one or more injections under the skin (subcutaneous), 1 time every two or four weeks.
- In asthma patients, a blood test for a substance called IgE must be performed prior to starting Xolair to determine the appropriate dose and dosing frequency.
- In patients with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.
- Patients must not decrease or stop taking any of their other asthma or hive medicine unless their healthcare providers tell them to.
- Patients may not see improvement in their symptoms right away after Xolair treatment.

Possible Side Effects of Xolair

Xolair may cause serious side effects, including:

- See, **"What is the most important information I should know about Xolair"** in the Xolair Medication Guide at <http://www.xolair.com> regarding the risk of anaphylaxis.
- **Cancer.** Cases of cancer were observed in some people who received Xolair.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive Xolair. This usually, but not always, happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by Xolair. Tell your healthcare provider right away if you have rash; chest pain; shortness of breath; or a feeling of pins and needles or numbness of your arms or legs.
- **Fever, muscle aches, and rash.** Some people who take Xolair get these symptoms one to five days after receiving a Xolair injection. If a patient has any of these symptoms, they must tell their healthcare provider.
- **Parasitic infection.** Some people who are at a high risk for parasite (worm) infections, get a parasite infection after receiving Xolair. The patient's healthcare provider can test the patient's stool to check if they have a parasite infection.
- **Heart and circulation problems.** Some people who receive Xolair have had chest pain, heart attack, blood clots in the lungs or legs, or temporary symptoms of weakness on one side of the body, slurred speech, or altered vision. It is not known whether this is caused by Xolair.

The most common side effects of Xolair:

- **In adults and children 12 years of age and older with asthma:** pain especially in the arms and legs, dizziness, feeling tired, skin rash, bone fractures and pain or discomfort of the ears.
- **In children 6 to less than 12 years of age with asthma:** common cold symptoms, headache, fever, sore throat, pain or discomfort of your ear, abdominal pain, nausea, vomiting and nose bleeds.
- **In people with chronic idiopathic urticaria:** nausea, headaches, swelling of the inside of the nose, throat or sinuses, cough, joint pain and upper respiratory tract infection.

These are not all the possible side effects of Xolair. Patients should call their doctor for medical advice about side effects.

Report side effects to the FDA at (800) FDA-1088 or <http://www.fda.gov/medwatch>. Report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at 888-669-6682.

Please see full Prescribing Information, including Medication Guide at <http://www.xolair.com> for additional Important Safety Information.

About Genentech



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Founded more than 40 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit <http://www.gene.com>.

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