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TEASE: a phase 2 clinical trial assessing the tolerability and effects of oral once-a-day ALK-001 on Stargardt disease

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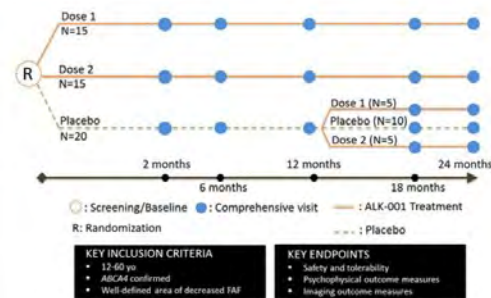
Purpose : Stargardt disease (STGD1) is the leading cause of inherited juvenile macular degeneration. The disease stems from mutations in *ABCA4*, a gene that encodes a vitamin A transport protein in the retina. Defective vitamin A transport results in accelerated formation of vitamin A dimers, thought to cause retinal degenerations including STGD1. The tolerability and effects of ALK-001 in Stargardt disease ("TEASE") study is the first of several prospective clinical trials to test the extent to which slowing the dimerization of vitamin A prevents the progression of STGD1.

Methods : ALK-001 is a vitamin A replacement: the chemical structure of ALK-001 is similar to that of vitamin A but 3 hydrogen atoms have been exchanged by deuterium. This change prevents ALK-001 from dimerizing. However, ALK-001 keeps all known functions of vitamin A. In preclinical evaluation, ALK-001 slows the rate of vitamin A dimerization approximately 4 to 5 fold but does not affect the visual cycle. TEASE is a 24-month, multicenter, randomized, double-masked, placebo-controlled study evaluating the effects of ALK-001 in up to 50 patients diagnosed with molecularly confirmed STGD1 aged between 12 and 60 years. Study subjects may have any visual acuity to enroll and must have a lesion of well-defined decreased signal on fundus autofluorescence imaging (FAF). TEASE subjects are randomly assigned to receive one of two doses of ALK-001 (30 subjects) or placebo (20 subjects) for one year. After one year, half of the subjects receiving placebo will be randomly crossed over to receive ALK-001 for the following 12 months, while all other subjects will continue receiving their initial treatment. A Data Monitoring Committee (DMC) reviews safety and efficacy data throughout the study.

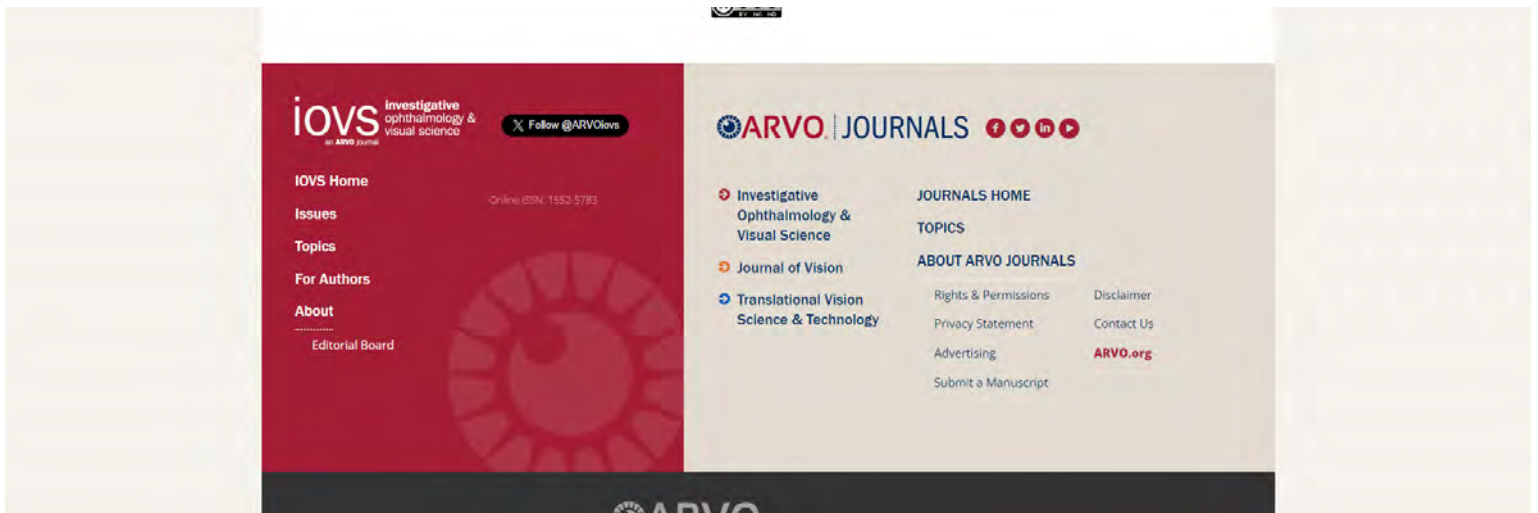
Results : Enrollment is ongoing. As of late 2015, 15 subjects have been enrolled, with the longest treatment duration of about 3 months. The median best corrected visual acuity at baseline was 63 letters (range, 26-85) in the best eye. Median age was 44 years (range, 20-59) and median disease duration 8 years (range, 1-25). Median lesion size in the best eye on FAF was 1.80 mm² (range, 0.25-17.74).

Conclusions : The TEASE study is one of the first FDA-regulated phase 2 clinical trials assessing a novel oral compound for retinal degenerative disease secondary to vitamin A dimerization, including STGD1.

This is an abstract that was submitted for the 2016 ARVO Annual Meeting, held in Seattle, Wash., May 1-5, 2016.


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ARVO Annual Meeting Abstract | July 2019

Stargardt disease ALK-001 phase 2 clinical trial: 12-month interim data

Hendrik P Scholl; Stephen H Tsang; Christine Nichols Kay; Thomas B. Connor; Michael B Gorin; Paul S. Bernstein; Byron L Lam; Zach Strecker; Justin Tyler Zaremba; Gabrielle DeBartolomeo; Ilyas Washington; Leonide Saad

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Abstract

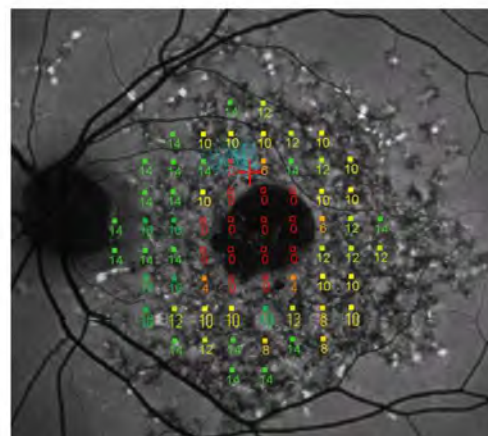
Purpose : Stargardt disease (STGD1) is the most prevalent inherited macular dystrophy. In the absence of an approved treatment, there is a growing interest and need for well-designed and controlled clinical trials. We present the design, baseline data, and one-year interim safety and pharmacokinetics of the prospective "TEASE" clinical trial.

Methods : TEASE is a two-year Phase 2 double-masked placebo-controlled study enrolling 50 subjects with ABCA4-related STGD1 and a well-delineated area of atrophy (Fig 1). The study drug ALK-001, is a selectively deuterated vitamin A used as vitamin A replacement and taken orally once-a-day. Deuterium slows vitamin A dimerization 4-5 fold without inhibiting the visual cycle. Subjects are randomized 2:1 ALK-001:placebo. After one year of treatment, 50% of placebo subjects crossover to ALK-001 in a masked and randomized fashion to compare atrophy progression before and after crossover. The primary endpoint is safety of two dose levels of ALK-001, while efficacy outcomes include atrophy lesion size by fundus autofluorescence (FAF), best-corrected visual acuity (BCVA), reading speed, dark adaptation and retinal sensitivity (microperimetry).

Results : 50 subjects (38 white; 28 female) have been randomized at 7 clinical sites. Median age was 46 years (range, 18-60) and disease duration 9 years (0-36). 48 of 50 subjects have completed the one-year follow-up visit. On average, 90% of vitamin A was replaced with deuterated vitamin A, which was maintained over time. ALK-001 was well-tolerated with no unexpected adverse reactions, no report of night blindness or impaired dark adaptation, and no clinically-significant increases in liver function tests or in total vitamin A (natural + deuterated). Atrophic lesions at baseline were bilateral in 74% of cases with a 5.1 mm² (0.3-31.6) median area, 46% and 52% of subjects had BCVA better than 20/40 or worse than 20/100, respectively. Mean retinal sensitivity was 8.3 dB (SD: 4.8). Deep scotomatous areas covered approximately 22% of a 20 deg diameter in the fovea (approx 0.1 mm² in 20 eyes).

Conclusions : The TEASE study is currently the largest, fully-enrolled clinical effort to slow or prevent the progression of STGD1. This feasible study design opens the avenue to similar studies. An expanded study, TEASE-2, is currently enrolling new participants (≥ 12 years old) in the USA.

This abstract was presented at the 2019 ARVO Annual Meeting, held in Vancouver, Canada, April 28 - May 2, 2019.





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Fig 1. FAF of a TEASE subject, displaying foveal retinal sensitivity

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BRINGING HEALTH INSIGHT

TREAT THE UNTREATABLE

Our pipeline of novel therapies, which is built on our RBP4 (Retinol Binding Protein 4) IP Portfolio, is focused on meeting the unmet needs of patients suffering from blindness, liver disease and diabetes.

Novel Therapy for

UNMET MEDICAL NEED

Belite Bio™ is a clinical stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting retinal degenerative eye diseases with significant unmet medical needs, such as atrophic age-related macular degeneration (AMD), commonly known as Geographic Atrophy (GA) in advanced dry AMD and autosomal recessive Stargardt disease, type 1, or STGD1.

Our lead candidate Tinalarebant, developed from our RBP4 intellectual property portfolio, is a novel oral therapy which is intended to reduce the accumulation of toxins in the eye that cause STGD1 and contribute to GA. We have completed a two-year Phase 2 study of Tinalarebant in adolescent STGD1 subjects, and are currently conducting a Phase 3 study (DRAGON) and a Phase 2/3 study (DRAGON II) in adolescent STGD1 subjects and a Phase 3 study (PHOENIX) in subjects with GA. Tinalarebant has obtained Orphan Drug Designation in the United States, Europe, and Japan, and has been granted the Rare Pediatric Disease (RPD) designation and the Fast Track Designation in the US and Sakigake (Pioneer Drug) Designation in Japan.

[MEET THE TEAM](#)

Tinalarebant
LBS-008

Bringing Hope to
INCURABLE BLINDNESS

Dry AMD / Stargardt Disease

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PHASE 3

LBS
009

Blocking the Path to
METABOLIC DISEASE

Non-Fatty Liver Disease / Type 2 Diabetes

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Tinlarebant (LBS-008) – Phase 3 trial for Geographic Atrophy (the “Phoenix” trial)

Recruitment Status: Recruiting

This trial is a phase 3, multicenter, double-masked, placebo-controlled, randomized, fixed-dose clinical study designed to evaluate the efficacy and safety of tinlarebant in patients with Geographic Atrophy associated with Dry AMD.

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Tinlarebant (LBS-008)-Phase 1b and Phase 2/3 trial for Stargardt Disease (the “DRAGON II” trial)

Recruitment Status: Recruiting

The DRAGON II trial is a combination of phase 1b open-label study to evaluate the pharmacokinetics and pharmacodynamics of Tinlarebant in Japanese adolescent STGD1 subjects and a phase 2/3, multicenter, double-masked, placebo-controlled, randomized study designed to evaluate the efficacy, safety and tolerability of Tinlarebant in adolescent STGD1 subjects.

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Tinlarebant (LBS-008) – Phase 3 trial for Stargardt Disease (the “Dragon” trial)

Recruitment Status: Active: not recruiting

This trial is to assess the efficacy and safety of Tinlarebant in adolescent subjects with childhood-onset Stargardt Disease.

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Tinlarebant (LBS-008) – Phase 1b/2 trial for Stargardt Disease

Status: Completed

This Phase 1b trial is to identify the optimal dose of Tinlarebant in adolescent subjects with childhood-onset Stargardt Disease. The Phase 1b trial is extended to a two year Phase 2 trial in assessing the safety and efficacy of Tinlarebant in adolescent subjects with childhood-onset Stargardt Disease.

[VIEW CLINICAL TRIAL INFORMATION](#)

Belite Bio™ Inc
12750 High Bluff Drive, Suite 475
San Diego CA, 92130 USA

INVESTOR RELATIONS

CORPORATE OVERVIEW

We are a clinical stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting currently retinal degenerative eye diseases with have significant unmet medical needs, such as Stargardt disease (STGD1) or Geographic Atrophy (GA) in advanced dry age-related macular degeneration (dry AMD), in addition to specific metabolic diseases.

We believe our lead product candidate, Tinarebant, or LBS-008 if approved, would provide a novel treatment option where there currently is none. Tinarebant is novel oral therapy which is intended to reduce the accumulation of toxins in the eye that cause STGD1 and contribute to GA, or advanced dry AMD. These toxins are by-products of the visual cycle, which is dependent on the supply of vitamin A (retinol) to the eye. Tinarebant works by reducing and maintaining levels of serum retinol binding protein 4 (RBP4), the sole carrier protein for retinol transport from the liver to the eye. By modulating the amount of retinol entering the eye, Tinarebant reduces the formation of these toxins. In clinical trials, Tinarebant has demonstrated its target specificity and potency that we believe could be clinically meaningful to treat STGD1 patients.

We have completed a two-year Phase 2 study of Tinarebant in adolescent STGD1 subjects, and are conducting a Phase 3 study (DRAGON) and a Phase 2/3 study (DRAGON II) in adolescent STGD1 subjects and a Phase 3 study (PHOENIX) in subjects with GA. DRAGON study is a multi-center, randomized, double masked, placebo controlled study to evaluate the safety and efficacy of Tinarebant in the treatment of adolescent STGD1 patients. DRAGON II trial is a combination of phase 1b open-label study to evaluate the pharmacokinetics and pharmacodynamics of Tinarebant in Japanese adolescent STGD1 subjects and a phase 2/3, multicenter, double-masked, placebo-controlled, randomized study designed to evaluate the efficacy, safety and tolerability of Tinarebant in adolescent STGD1 subjects. PHOENIX study is a multi-center, randomized, double-masked, placebo-controlled study to evaluate the safety and efficacy of Tinarebant in GA subjects.

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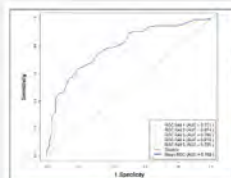
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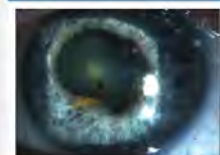


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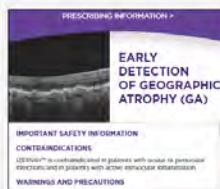
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Retina January 2024

Visual Sensitivity Loss in **Geographic Atrophy**: Structure–Function Evaluation Using Defect-Mapping Microperimetry **OPEN ACCESS**

PDF

Zhichao Wu; Xavier Hadoux; Maxime Jannaud; Emily K. Glover; Erin E. Geer; Lauren A. B. Hodgson; Peter van Wijngaarden; Robyn H. Guymer

TAGS: age-related macular degeneration, nonexudative, eye, vision
Invest. Ophthalmol. Vis. Sci. 2024; 65(1):36. <https://doi.org/10.1167/iov.65.1.36>

Includes: Supplemental Content

ARVO Annual Meeting Abstract April 2010

Topical OT-551 for Treating Geographic Atrophy: Phase II Results **FREE**

P. Sternberg; P. J. Rosenfeld; J. S. Slakter; J. M. Koester; A. Reeves

Invest. Ophthalmol. Vis. Sci. 2010; 51(13):6416.

Articles December 2018

Oral Dextromethorphan for the Treatment of Diabetic Macular Edema: **Results From a Phase I/II Clinical Study** **OPEN ACCESS**

PDF

David J. Valenti; Wai T. Wong; Emily Y. Chew; Catherine A. Cukras

TAGS: dextromethorphan, diabetic macular edema, eye
Trans. Vis. Sci. Tech. 2018; 7(6):24. <https://doi.org/10.1167/tvst.7.6.24>

Includes: Supplemental Content.

ARVO Annual Meeting Abstract April 2010

Topical Administration of Anti-Oxidant, OT-551 for the Treatment of Geographic Atrophy: Results of a Phase I/II Clinical Trial **FREE**

W. T. Wong; W. Karm; D. Cunningham; E. Y. Chew; F. L. Ferris, III

Invest. Ophthalmol. Vis. Sci. 2010; 51(13):6418.

Clinical Trials April 2013

Treatment of **Geographic Atrophy** With Subconjunctival Sirolimus: **Results of a Phase I/II Clinical Trial** **FREE**

PDF

Wai T. Wong; Samuel Dresner; Farzin Forooghian; Tanya Glasec; Lauren Doss; Mei Zhou; Denise Cunningham; Katherine Shimel; Molly Harrington; Keni Hammel; Catherine A. Cukras; Frederick L. Ferris; Emily Y. Chew

TAGS: atrophy, eye, rapamycin, visual acuity, follow-up, drusen
Invest. Ophthalmol. Vis. Sci. 2013; 54(4):2941-2950. <https://doi.org/10.1167/iov.13-11650>

Includes: Supplemental Content

Clinical Trials December 2010

Treatment of **Geographic Atrophy** by the **Topical** Administration of **OT-551: Results of a Phase II Clinical Trial** **FREE**

PDF

Wai T. Wong; Wayne Karm; Denise Cunningham; Molly Harrington; Keni Hammel; Catherine B. Meyerle; Catherine Cukras; Emily Y. Chew; Srinivas R. Sadda; Frederick L. Ferris

TAGS: administration, topical, atrophy, eye, phase 2 clinical trials, visual acuity, drusen, contrast sensitivity
Invest. Ophthalmol. Vis. Sci. 2010; 51(12):6131-6139. <https://doi.org/10.1167/iov.10-5637>

Clinical and Epidemiologic Research February 2011

Changes in Retinal Sensitivity in **Geographic Atrophy** Progression as Measured by Microperimetry **FREE**

PDF

Annal D. Meleth; Pradeep Mettu; Elvira Agrón; Emily Y. Chew; Srinivas R. Sadda; Frederick L. Ferris; Wai T. Wong

TAGS: atrophy, eye, diagnostic imaging, follow-up
Invest. Ophthalmol. Vis. Sci. 2011; 52(2):1119-1126. <https://doi.org/10.1167/iov.10-6075>

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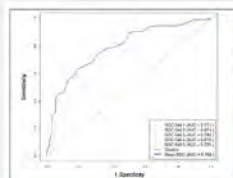
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Understanding the Nuts and Bolts of Clinical Research

Medical studies are loaded with specialized terms and tools. Here's what they mean and why they matter.

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INDICATIONS AND USAGE
XDEMZY (lotilaner ophthalmic solution) 0.25% is indicated for the treatment of Demodex (Demodex) blepharitis.

IMPORTANT SAFETY INFORMATION:

16 HOURS
of precise vision and dependable comfort!

THE NEWS FEED

Study Identifies Normative Values for Macula Vessel Density and FAZ on OCT-A
September 20, 2024

Phentolamine Phase III Data Shows Success in Quickly Reversing Dilation
September 18, 2024

Ultra-Widefield FA Imaging Best for Assessing DR Progression Risk
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These options can expand access and patient convenience but must be matched with protocols and public awareness campaigns that preserve the value of a comprehensive exam.

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Reader Survey: What's On Your Tech Shopping List?
Find out what matters most to optometrists when adding tools and techniques to their practices.

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Devices You Might Not Have: Are They a Good Fit?
Experts weigh in on how advanced tools can help with specific clinical responsibilities, providing you clarity on whether their benefits will serve your specific needs.

ANNUAL TECHNOLOGY REPORT
Prospects for Remote Monitoring in Eye Care
Clinicians can improve the quality of services provided to patients from underserved populations and extend the surveillance of disease status beyond their clinics.

PHARMACEUTICALS
Can You Spot these Drug-induced Ocular Side Effects?
Consider these four cases involving toxic optic neuropathy and maculopathy to learn more about the potential mishaps of systemic meds.

LOW VISION
Geographic Atrophy: Looking Beyond VA
A discussion on the many other markers of visual function and quality in these patients, as well as the options available to help them see better.

CLINICAL RESEARCH
Understanding the Nuts and Bolts of Clinical Research
Medical studies are loaded with specialized terms and tools. Here's what they mean and why they matter.

DEPARTMENTS

URGENT CARE
Hidden in Good Sight
Unilateral mild blur leads to diagnosis of primary vitreous detachment.

CLINICAL QUANDARIES
Pucker Up
Gain the confidence to treat patients with epiretinal membranes.

RETINA QUIZ
A Bloody Mess
This clinical diagnosis is based on characteristic fundus features.

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A Breakthrough in Nutritional Supplementation for Dry Eyes

Annual Contact Lenses and Lens Care Guide - 2024

Practical Matters in Myopia Management - 2024

July Ophthalmic Product Guide

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EARLY DETECTION OF GEOGRAPHIC ATROPHY (GA)
IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
USE ONLY in patients with central or peripheral geographic atrophy (GA) and no other retinal disease.
WARNINGS AND PRECAUTIONS

REVIEW OF CORNEA & CONTACT LENSES



September/October 2024

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Novices may be unaware of certain intricacies these lenses possess, which can make a big difference in outcomes.

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Preservatives in Eye Care: Intrepid Eye Society Consensus Discussion
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xdemy
0.25% solution

Demodex mites are everywhere^{1,2}

-58%* of eye care patients in the US may have Demodex blepharitis (DB)

*BASED ON 2023 Survey. A cross-sectional study involving 100 eye care professionals (ECPs) in the US. The survey found that 58% of ECPs reported having at least one patient with DB in the last 12 months. The survey also found that 58% of ECPs reported having at least one patient with DB in the last 12 months.

INDICATIONS AND USAGE
XDEMY (lotilaner ophthalmic solution) 0.25% is indicated for the treatment of Demodex blepharitis.

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Fifth Annual Guide to Retinal Disease

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MILLIONS OF AMERICANS suffer from hematological disorders, which can cause significant ocular complications in our patients.

What's New in Clinical Trials for Treatment of Dry AMD

Posterior Vitreous Detachment: A Common Process with Potential for Ocular Morbidity

How to Successfully Incorporate Retinal Technology into Your Practice

Sherrel A. Reynolds, O.D., F.A.A.O., and Julie Rodman, O.D., F.A.A.O.
Hematological Disorders and the Retina

Thomas J. Stokkermans, O.D., Ph.D., F.A.A.O.
What's New in Clinical Trials for Treatment of Dry AMD

Diana L. Shechtman, O.D., F.A.A.O., Diane E. Calderon, O.D., F.A.A.O.
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Jeffrey D. Gerson, O.D., F.A.A.O., Joseph J. Pizzimenti, O.D., F.A.A.O.
Pamela A. Lowe, O.D., F.A.A.O. and William Jones, O.D., F.A.A.O.
How to Successfully Incorporate Retinal Technology into Your Practice

PREScribing INFORMATION

izervay
(bimatoprost) ophthalmic solution 0.03%

MEANS EARLY TREATMENT WITH IZERVAY

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
IZERVAY is contraindicated in patients with ocular or genital infections and in patients with active intraocular inflammation.

WARNINGS AND PRECAUTIONS

ADDITIONAL PUBLICATIONS

Wellness Essentials for Clinical Practice - 4th Edition
In this special annual supplement, members of the Ocular Wellness & Nutrition Society (OWNS) contribute 10 articles on the intersection of physical wellness and eye health.
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Treatment Strategy With Gene Editing for Late-Onset Retinal Degeneration Caused by a Founder Variant in C1QTNF5 OPEN ACCESS

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Randa T. H. Li; Alejandro J. Roman; Alexander Sumaroka; Chloe M. Stanton; Malgorzata Swider; Alexandra V. Garafalo; Elise Heon; Ajoy Vincent; Alan F. Wright; Roly Megaw; Tomas S. Aleman; Andrew C. Browning; Baijean Dhillon; Artur V. Cideciyan

TAGS: gene editing, photoreceptors, retina, retinal degeneration, tissue degeneration, diagnostic imaging, retinal cone, fovea centralis, natural history, eye
Invest. Ophthalmol. Vis. Sci., 2023; 64(15):33. <https://doi.org/10.1167/iov.64.15.33>

Includes: Supplemental Content

Retina December 2022

Photoreceptor Function and Structure in Autosomal Dominant Vitelliform Macular Dystrophy Caused by BEST1 Mutations OPEN ACCESS

 PDF

Artur V. Cideciyan; Samuel G. Jacobson; Malgorzata Swider; Alexander Sumaroka; Rebecca Sheplock; Arun K. Krishnan; Alexandra V. Garafalo; Karina E. Guziewicz; Gustavo D. Aguirre; William A. Beltran; Elise Heon

TAGS: best1 gene, eye, mutation, photoreceptors, retina, retinal cone, rod photoreceptors, vitelliform dystrophy, fovea centralis, vision
Invest. Ophthalmol. Vis. Sci., 2022; 63(13):12. <https://doi.org/10.1167/iov.63.13.12>

Lecture March 2022

Nourishing Better Vision: The ARVO 2021 Mildred Weisenfeld Award Lecture OPEN ACCESS

 PDF

Paul S. Bernstein

TAGS: awards and prizes, carotenoids, retinoids, science of nutrition, vision, polyunsaturated fatty acids, eye, diet, macular pigment, retina
Invest. Ophthalmol. Vis. Sci., 2022; 63(3):13. <https://doi.org/10.1167/iov.63.3.13>

Review June 2020

Advancing Clinical Trials for Inherited Retinal Diseases: Recommendations from the Second Monaciano Symposium OPEN ACCESS

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Debra A. Thompson; Alessandro Iannaccone; Robin R. Ali; Vadim Y. Arshavsky; Isabelle Audo; James W. B. Bainbridge; Cagri G. Besirli; David G. Birch; Kari E. Branham; Artur V. Cideciyan; Steven P. Daiger; Deniz Dalkara; Jacques L. Duncan; Abigail T. Fahim; John G. Flannery; Roberto Gattaglia; John R. Heckenlively; Elise Heon; K. Thirun Jayasundera; Naheed W. Khan; Henry Klassen; Bart P. Leroy; Robert S. Molday; David C. Musch; Mark E. Pennesi; Simon M. Petersen-Jones; Eric A. Pierce; Rajesh C. Rao; Thomas A. Reh; Jose A. Sahel; Dror Sharon; Paul A. Sieving; Enrica Strettoi; Paul Yang; David N. Zacks; The Monaciano Consortium

TAGS: outcome measures, retinal diseases, surrogate endpoints, genetics, vision, natural history, ethics, gene therapy
Trans. Vis. Sci. Tech., 2020; 9(1):2. <https://doi.org/10.1167/tvst.9.1.2>

ARVO Annual Meeting Abstract May 2007

Is the Vitamin A Treatment Safe for Retinal Degeneration Caused by Mutations in ABCA4 Gene? FREE

G. H. Travis; J. H. Peng; J. Hu; D. Bok; S. Nusinowitz; R. A. Radu

Invest. Ophthalmol. Vis. Sci., 2007; 48(13):5638.

Perspective July 2018

Inherited Retinal Degenerations: Current Landscape and Knowledge Gaps OPEN ACCESS

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Jacque L. Duncan; Eric A. Pierce; Amy M. Laster; Stephen P. Daiger; David G. Birch; John D. Ash; Alessandro Iannaccone; John G. Flannery; José A. Sahel; Donald J. Zack; Marco A. Zarbin; and the Foundation Fighting Blindness Scientific Advisory Board

TAGS: genes, genetics, retinal degeneration, comprehension, animal model, mutation
Trans. Vis. Sci. Tech., 2018; 7(4):6. <https://doi.org/10.1167/tvst.7.4.6>

Review September 2017

Towards Treatment of Stargardt Disease: Workshop Organized and Sponsored by the Foundation Fighting Blindness OPEN ACCESS

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Avery E. Sears; Paul S. Bernstein; Artur V. Cideciyan; Carel Hoyng; Peter Charbel Issa; Krzysztof Palczewski; Philip J. Rosenfeld; Srinivas Sadda; Ulrich Schraermeyer; Janet R. Sparrow; Ilyse Washington; Hendrik P.N. Scholl

TAGS: blindness, stargardt's disease
Trans. Vis. Sci. Tech., 2017; 6(5):6. <https://doi.org/10.1167/tvst.6.5.6>

Review March 2016

Potential Therapeutic Agents Against Retinal Diseases Caused by Aberrant Metabolism of Retinoids OPEN ACCESS

 PDF

Xin Liu; Jingmei Chen; Zhai Liu; Jie Li; Ke Yao; Yalin Wu

TAGS: metabolism, retinal diseases, retinoids
Invest. Ophthalmol. Vis. Sci., 2016; 57(3):1017-1030. <https://doi.org/10.1167/iov.15.18429>

Retina June 2016

Automated Light- and Dark-Adapted Perimetry for Evaluating Retinitis Pigmentosa: Filling a Need to Accommodate Multicenter Clinical Trials OPEN ACCESS

 PDF

David B. McGugan, III; Alejandro J. Roman; Artur V. Cideciyan; Rodrigo Matsui; Michaela L. Gruzensky; Rebecca Sheplock; Samuel G. Jacobson

TAGS: perimetry, retinal cone, retinitis pigmentosa, rod photoreceptors, visual fields
Invest. Ophthalmol. Vis. Sci., 2016; 57(7):3118-3128. <https://doi.org/10.1167/iov.16-19302>

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Retina March 2016

Fluorescence Lifetime Imaging in Stargardt Disease: Potential Marker for Disease Progression OPEN ACCESS

 PDF

Chantal Dysic Sebastian Wolf; Katja Hatz; Martin S. Zinkernagel

TAGS: diagnostic imaging, disease progression, fluorescence, stargardt's disease, autofluorescence, atrophic condition of skin
Invest. Ophthalmol. Vis. Sci., 2016; 57(3):832-841. <https://doi.org/10.1167/iov.15-18033>

Includes: Supplemental Content

Biochemistry and Molecular Biology December 2014

Targeted Fatty Acid Synthesis in Higher Eukaryotes Tuna OPEN ACCESS

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Kinga M. Bujakowski; Mark Consugar; Emily Place; Shyana Harper; Jacyln Lena; Daniel G. Taub; Joseph White; Daniel Navarro-Gomez; Carol Weigel DiFranco; Michael H. Farkas; Xiaowu Gai; Eliot L. Berson; Eric A. Pierce TAGS: exons, genes, mutation, usher syndrome, cohort studies, massively-parallel genome sequencing <i>Invest. Ophthalmol. Vis. Sci.</i>, 2014; 55(12):8488-8496. https://doi.org/10.1167/iov.14-15169 Includes: Supplemental Content	
Lecture October 2014 Chemistry and Biology of the Initial Steps in Vision: The Friedenwald Lecture FREE Krzysztof Palczewski TAGS: proteins, retinoids, rhodopsin, science of chemistry, vision, mice, diagnostic imaging, tissue membrane, retina, phototransduction <i>Invest. Ophthalmol. Vis. Sci.</i>, 2014; 55(10):6651-6672. https://doi.org/10.1167/iov.14-15502	PDF
Retina May 2014 Quantitative Fundus Autofluorescence in Recessive Stargardt Disease FREE Tomas R. Burke; Tobias Droncker; Russell L. Woods; Jonathan P. Greenberg; Jana Zernant; Stephen H. Tsang; R. Theodore Smith; Rando Allikmets; Janet R. Sparrow; François C. Delion TAGS: autofluorescence, eye, fundus autofluorescence imaging, phenotype, stargardt's disease, mutation, genotype, lipofuscin <i>Invest. Ophthalmol. Vis. Sci.</i>, 2014; 55(5):2841-2852. https://doi.org/10.1167/iov.13-13624 Includes: Supplemental Content	PDF
Research Opportunities April 2014 Drug and Gene Delivery to the Back of the Eye: From Bench to Bedside FREE Cheryl L. Rowe-Rendleman; Shelley A. Durazo; Uday B. Kompella; Kay D. Rittenhouse; Adriana Di Polo; Alan L. Weiner; Hans E. Grossniklaus; Muna I. Naash; Alfred S. Lewin; Alan Horsager; Henry F. Edelhauser TAGS: drug delivery systems, eye, genes, animal model, gene therapy, proteins, nanoparticles, hydrogels, retina, molecule <i>Invest. Ophthalmol. Vis. Sci.</i>, 2014; 55(4):2714-2730. https://doi.org/10.1167/iov.13-13707	PDF
Retina June 2013 Transduction of Photoreceptors With Equine Infectious Anemia Virus Lentiviral Vectors: Safety and Biodistribution of StarGen for Stargardt Disease FREE Katie Binley; Peter Widdowson; Julie Loader; Michelle Kelleher; Sharifah Iqbal; Georgina Ferrige; Jackie de Belin; Marie Carlucci; Diana Angeli-Manning; Felicity Hurst; Scott Ellis; James Miskin; Alcides Fernandes; Paul Wong; Rando Allikmets; Christopher Bergstrom; Thomas Aaberg; Jong Yan; Jan Kong; Peter Gouras; Annick Prefontaine; Mark Vezina; Martin Bussières; Stuart Naylor; Kynacos A. Mitrophanous TAGS: disease vectors, equine infectious anemia virus, eye, gene transfer techniques, lentiviral vector, macaca, oryctolagus cuniculus, photoreceptors, safety, spatial vectors <i>Invest. Ophthalmol. Vis. Sci.</i>, 2013; 54(6):4061-4071. https://doi.org/10.1167/iov.13-11871	PDF
Retina October 2011 Retinal Disease Course in Usher Syndrome 1B Due to MYO7A Mutations FREE Samuel G. Jacobson; Artur V. Cideciyan; Dan Gibbs; Alexander Sumaroka; Alejandro J. Roman; Tomas S. Aleman; Sharon B. Schwartz; Melani B. Olivaes; Robert C. Russell; Janet D. Steinberg; Margaret A. Kenna; William J. Kimberling; Heidi L. Rehm; David S. Williams TAGS: kinetics, mutation, perimetry, retina, retinal cone, retinal diseases, rod photoreceptors, usher syndrome, vision, photoreceptors <i>Invest. Ophthalmol. Vis. Sci.</i>, 2011; 52(11):7924-7936. https://doi.org/10.1167/iov.11-8313 Includes: Supplemental Content	PDF
Biochemistry and Molecular Biology December 2005 Reductions in Serum Vitamin A Arrest Accumulation of Toxic Retinal Fluorophores: A Potential Therapy for Treatment of Lipofuscin-Based Retinal Diseases FREE Roxana A. Radu; Yun Han; Tam V. Bui; Steven Nusinowitz; Dean Bok; Jay Lichter; Ken Widder; Gabriel H. Travis; Nathan L. Mata TAGS: lipofuscin, mice, retinal diseases, retinoids, vitamin a, autofluorescence, dimethyl sulfoxide <i>Invest. Ophthalmol. Vis. Sci.</i>, 2005; 46(12):4393-4401. https://doi.org/10.1167/iov.05-0820	PDF
Biochemistry and Molecular Biology January 2007 Light Induces Programmed Cell Death by Activating Multiple Independent Proteases in a Cone Photoreceptor Cell Line FREE Yogita Kanar; Gennadiy Moseyev; Neeraj Agarwal; Jian-Xing Ma; Muayyad R. Al-Ubaidi TAGS: apoptosis, caspases, cell death, cell lines, endopeptidases, peptide hydrolases, proteins, retinal cone, stress, light exposure <i>Invest. Ophthalmol. Vis. Sci.</i>, 2007; 48(1):40-51. https://doi.org/10.1167/iov.06-0592 Includes: Supplemental Content	PDF

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ARVO Annual Meeting Abstract May 2008

Docosahexaenoic Acid Does Not Improve Visual Function in Patients With Autosomal Recessive Stargardt Disease FREE

R. C. Caruso; E. Agron; P. Lopez; L. M. Reuter; J. Back; P. A. Sieving; I. M. MacDonald
Invest. Ophthalmol. Vis. Sci.. 2008; 49(13):4688.

Articles October 2020

A Ketogenic & Low-Protein Diet Slows Retinal Degeneration in rd10 Mice OPEN ACCESS

Renee C. Ryalla; Samuel J. Huang; Dahlia Wafai; Claire Bernert; William Steele; Makayla Six; Shasank Bonthala; Hope Titus; Paul Yang; Melanie Gillingham; Mark E. Pennesi

TAGS: diet, diet, protein-restricted, mice, proteins, retina, retinal degeneration, electroretinography, serum albumin
Trans. Vis. Sci. Tech.. 2020; 9(11):18. <https://doi.org/10.1167/tvst.9.11.18>

Includes: Multimedia, Supplemental Content

Perspective July 2018

Inherited Retinal Degenerations: Current Landscape and Knowledge Gaps OPEN ACCESS

Jacque L. Duncan; Eric A. Pierce; Amy M. Laster; Stephen P. Daiger; David G. Birch; John D. Ash; Alessandro Iannaccone; John G. Flannery; José A. Sahel; Donald J. Zack; Marco A. Zarbin; and the Foundation Fighting Blindness Scientific Advisory Board

TAGS: genes, genetics, retinal degeneration, comprehension, animal model, mutation
Trans. Vis. Sci. Tech.. 2018; 7(4):6. <https://doi.org/10.1167/tvst.7.4.6>

Articles June 2018

Intraobserver Repeatability and Interobserver Reproducibility of Ellipsoid Zone Measurements in Retinitis Pigmentosa OPEN ACCESS

Margaret R. Stramp; Alison L. Hickenpahl; Brian P. Higgins; Sergey Tarima; Alexia Visotcky; Kimberly E. Stepien; Christine N. Kay; Joseph Carroll

TAGS: retinitis pigmentosa, spectral domain-optical coherence tomography, usher syndrome
Trans. Vis. Sci. Tech.. 2018; 7(3):13. <https://doi.org/10.1167/tvst.7.3.13>

Includes: Multimedia, Supplemental Content

Articles July 2016

Outer Retinal Changes Including the Ellipsoid Zone Band in Usher Syndrome 1B due to MYO7A Mutations OPEN ACCESS

Alexander Sumaroka; Rodrigo Matsui; Artur V. Cideciyan; David B. McGuigan, III; Rebecca Shepleck; Sharon B. Schwartz; Samuel G. Jacobson

TAGS: mutation, optical coherence tomography, retina, usher syndrome, vision, rod photoreceptors, fovea centralis
Invest. Ophthalmol. Vis. Sci.. 2016; 57(9):OCT253-OCT261. <https://doi.org/10.1167/iov.15-18860>

Genetics September 2014

Molecular Diagnostic Testing by eyeGENE: Analysis of Patients With Hereditary Retinal Dystrophy Phenotypes Involving Central Vision Loss FREE

Akhila Alapatt; Kerry Goetz; John Suic; Mili Navani; Amani Al-Tarouti; Thirani Jayasundera; Santa J. Timminis; Pauline Lee; Radha Ayyagari

TAGS: blindness, diagnostic techniques and procedures, genes, hereditary retinal dystrophy, mutation, phenotype, retinal dystrophies, vitelliform dystrophy, retinitis pigmentosa, progressive cone-rod dystrophy
Invest. Ophthalmol. Vis. Sci.. 2014; 55(9):5520-5521. <https://doi.org/10.1167/iov.14-14359>

Retina April 2012

Dietary Docosahexaenoic Acid Supplementation Prevents Age-Related Functional Losses and A2E Accumulation in the Retina FREE

Blake Dornstauder; Myoung Suh; Sharee Kuny; Frédéric Gaillard; Ian M. MacDonald; Michael T. Clandinin; Yves Sauvé

TAGS: diet, docosahexaenoic acids, mice, retina, retinal degeneration, electroretinography
Invest. Ophthalmol. Vis. Sci.. 2012; 53(4):2256-2265. <https://doi.org/10.1167/iov.11-8569>

Clinical and Epidemiologic Research March 2013

Genetic Determinants of Macular Pigments in Women of the Carotenoids in Age-Related Eye Disease Study FREE

Kristin J. Meyers; Elizabeth J. Johnson; Paul S. Bernstein; Sudha K. Iyengar; Corinne D. Engelman; Chitra K. Karkic; Zhe Liu; Robert P. Igo, Jr.; Barbara Trutt; Michael L. Klein; D. Max Snodderly; Barbara A. Blodi; Karen M. Gehrs; Gloria E. Sarto; Robert B. Wallace; Jennifer Robinson; Erin S. LeBlanc; Gregory Hageman; Lesley Tinker; Julie A. Mares

TAGS: carotenoids, genes, pigment, genetics, eye diseases, single nucleotide polymorphism, metabolism
Invest. Ophthalmol. Vis. Sci.. 2013; 54(3):2333-2345. <https://doi.org/10.1167/iov.12-10867>

Includes: Supplemental Content

Retinal Cell Biology August 2006

Haploinsufficiency Is Not the Key Mechanism of Pathogenesis in a Heterozygous Elov4 Knockout Mouse Model of STGD3 Disease FREE

Dorit Raz-Prag; Radha Ayyagari; Robert N. Farnis; Md Nawajes A. Mandal; Viduyilatha Vasireddy; Sharon Majchrzak; Andrea L. Webber; Ronald A. Bush; Norman Salem, Jr; Konstantin Petrukhin; Paul A. Sieving

TAGS: fatty acids, haploinsufficiency, heterozygote, mice, mice, knockout, pathogenesis, proteins, retina, electroretinography, genes
Invest. Ophthalmol. Vis. Sci.. 2006; 47(8):3603-3611. <https://doi.org/10.1167/iov.05-1527>

Retina March 2007

Macular Pigment and Lutein Supplementation in ABCA4-Associated Retinal Degenerations FREE

Tomas S. Aleman; Artur V. Cideciyan; Elizabeth A. M. Windsor; Sharon B. Schwartz; Malgorzata Swider; John D. Peter; Alexander Sumaroka; Alexander V. Pankratov; Keith C. Prescott; Keith M. Cooper; Thomas M. Forrester

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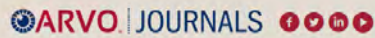
TAGS: lutein, pigment, retinal degeneration
Invest. Ophthalmol. Vis. Sci. 2007; 48(3):1319-1329. <https://doi.org/10.1167/iov.06-0764>

Index December 2007

2007 Subject Index **FREE**



TAGS: mice, glaucoma, cornea
Invest. Ophthalmol. Vis. Sci. 2007; 48(12):5843-5875.



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Gildeuretinol Arrested Stargardt Disease, The TEASE-3 Study

NEWSROOM

PRESS RELEASES

PUBLICATIONS

January 10, 2024

Alkeus Pharmaceuticals Presents Positive Interim Data Showing Gildeuretinol Halted Stargardt Disease Progression

CAMBRIDGE, Mass. - Alkeus Pharmaceuticals, Inc. today announced positive interim data showing gildeuretinol halted Stargardt disease progression for up to six years. In its ongoing TEASE-3 clinical trial in early-stage Stargardt disease, the first three teenage patients enrolled in TEASE-3 and treated with oral gildeuretinol acetate remained asymptomatic and free of disease progression for their treatment duration ranging between two (one patient) and six years (two patients). In the absence of treatment, the patients were projected to begin experiencing vision loss within two years, following the same disease trajectory as that of their respective older siblings with identical genetic mutations who had not been treated with gildeuretinol.

[Learn More >](#)

December 21, 2023

Alkeus Pharmaceuticals to Present at the 42nd Annual J.P. Morgan Healthcare Conference on Jan. 10, 2024

CAMBRIDGE, Mass. - Alkeus Pharmaceuticals, Inc. today announced that Joshua Boger, Ph.D., Executive Chairman, and Leonide Saad, Ph.D., President and Chief Executive Officer, will provide a corporate update and present the latest information on its late-stage investigational therapy to prevent blindness, during the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco on Wednesday, Jan. 10, 2024, at 11:30 a.m. PST at The Westin St. Francis Hotel.

[Learn More >](#)

November 3, 2023

Alkeus Pharmaceuticals Presents Positive Gildeuretinol Trial Results at American Academy of Ophthalmology, Demonstrating Significant Slowing of Retinal Atrophic Lesions in Stargardt Disease

SAN FRANCISCO - Alkeus Pharmaceuticals, Inc. today announced positive data from its TEASE-1 study, a randomized, double-masked, placebo-controlled clinical trial investigating the effects of gildeuretinol (ALK-001) in patients with Stargardt disease. Christine Kay, M.D., of Vitreo Retinal Associates Florida, will present the trial results during the 2023 American Academy of Ophthalmology (AAO) Retina Subspecialty Day.

[Learn More >](#)

June 5, 2023

Alkeus Announces \$150 Million Series B Financing, Supporting Rapid Registration Path for gildeuretinol (ALK-001) in the Treatment of Stargardt Disease

CAMBRIDGE, Mass. - Alkeus Pharmaceuticals, Inc. announced today that it has raised a \$150 million Series B financing to support the registration and launch of gileuretinol (ALK-001), a potential disease-modifying, precision medicine for the treatment of Stargardt disease, a leading genetic cause of blindness in children and young adults. The financing was led by Bain Capital Life Sciences, with additional participation by TCGX, Wellington Management and Sofinnova Investments. Alkeus also announced today that Joshua Boger, Ph.D., a biotech industry pioneer and the founder of Vertex Pharmaceuticals, has joined Alkeus as Executive Chairman.

[Learn More >](#)

Alkeus Pharmaceuticals, Inc.

Cambridge, MA
General: info@alkeuspharma.com



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September 2024	 Company Presentation

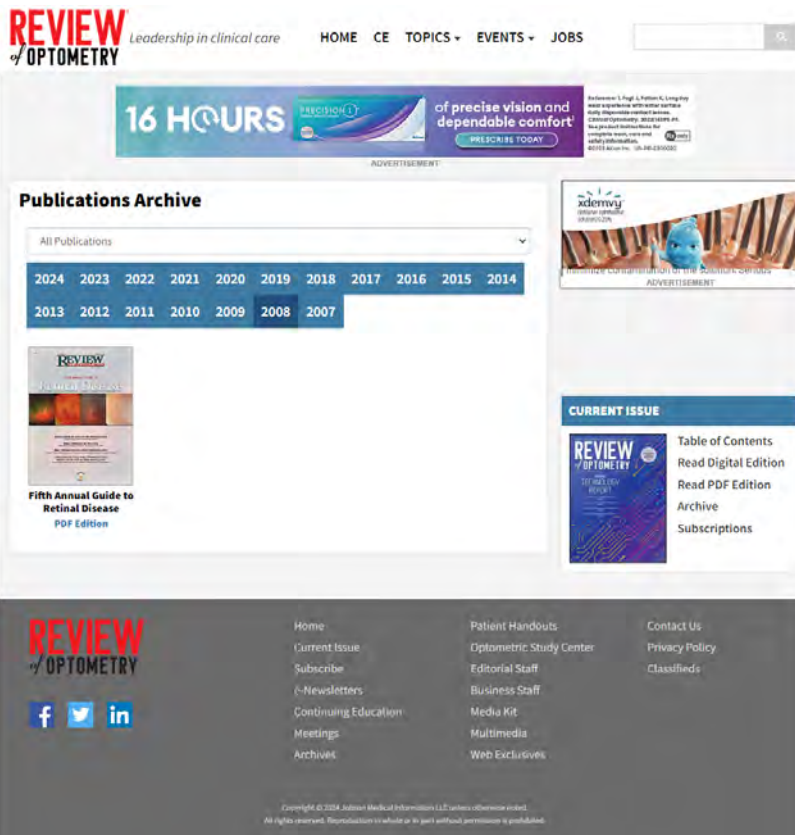


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PRESS RELEASE

Alkeus Announces \$150 Million Series B Financing, Supporting Rapid Registration Path for gildeuretinol (ALK-001) in the Treatment of Stargardt Disease

[Download Press Release](#)

For all inquiries, please contact:

David Setboun, PharmD, MBA
Chief Operating Officer
media01@alkeuspharma.com

Vertex Founder and Industry Pioneer Joshua Boger, Ph.D. named as Executive Chairman of Alkeus

CAMBRIDGE, Mass., Jun. 5, 2023 - Alkeus Pharmaceuticals, Inc. today announced that it has raised a \$150 million Series B financing to support the registration and launch of gildeuretinol (ALK-001), a potential disease-modifying, precision medicine for the treatment of Stargardt disease, a leading genetic cause of blindness in children and young adults. The financing was led by Bain Capital Life Sciences, with additional participation by TCGX, Wellington Management and Sofinnova Investments. Alkeus also announced today that Joshua Boger, Ph.D., a biotech industry pioneer and the founder of Vertex Pharmaceuticals, has joined Alkeus as Executive Chairman.

"The proceeds from this \$150 million financing will allow Alkeus to expand our team and drive gildeuretinol towards NDA submission and FDA approval as rapidly as possible," said Leonide Saad, Ph.D., CEO, President, and Co-Founder of Alkeus. "I am thrilled to work hand in hand with Joshua as Executive Chairman as we build a patient-focused company. Joshua's deep experience leading the successful development and commercialization of transformative medicines will be of tremendous value to Alkeus during this period of organizational growth, in preparation for the launch of gildeuretinol."

Stargardt disease is a leading cause of blindness in children and young adults, affecting more than 30,000 people in the U.S. and more than 150,000 worldwide. Patients with Stargardt disease are typically born with normal vision, but mutations in the ABCA4 gene lead to accelerated dimerization — or clumping — of vitamin A in the eye, causing damage to the retina and subsequent progressive vision loss, starting as early as five years of age. Gildeuretinol is the first and only medicine in clinical development to address the underlying mechanism of Stargardt disease by substantially reducing vitamin A dimerization in the eye, without any impact on normal vision. Phase 2 clinical data has shown a statistically and clinically meaningful slowing of retinal damage in Stargardt patients. The U.S. FDA has granted Breakthrough Therapy Designation and Orphan Drug Designation to gildeuretinol (ALK-001). Alkeus plans to submit an NDA for approval of gildeuretinol in 2024.

"Stargardt is a progressive, debilitating disease that leads inevitably to devastating vision loss. The genetic cause is well characterized, but to date there is no effective treatment," said Joshua Boger, Ph.D., Executive Chairman of Alkeus. "Leonide and the Alkeus team have brought gildeuretinol from the lab all the way to positive and compelling clinical data across multiple stages of the disease, including a Phase 2 placebo-controlled trial in patients with advanced disease, where we have reported a statistically- and clinically-significant slowing of disease. Additional clinical data show halting of disease in patients, including children."

Dr. Boger continued, "We are now poised to make this transformative medicine a reality for all Stargardt patients."

About Gildeuretinol (ALK-001)

Gildeuretinol was designed by researchers as a novel, specifically deuterated form of vitamin A that greatly reduces vitamin A dimerization, with the potential to slow or halt the progression of vision loss in Stargardt patients without disrupting the visual cycle. In preclinical studies, gildeuretinol decreased vitamin A dimerization by more than 80% and prevented development of blindness in a genetic animal model of the disease. In a 2-year, double-blind, placebo-controlled Phase 2 study (n = 50) in Stargardt patients with advanced disease, treatment with gildeuretinol once a day as a pill resulted in slowing of retinal damage as compared to placebo, based on observed growth rates in atrophic lesions as measured by fundus autofluorescence (FAF). The drug was well tolerated, with safety consistent with the well-characterized profile of vitamin A. In children and young adults with earlier stage Stargardt disease, gildeuretinol appeared to halt the disease process, preventing any further retinal damage and vision loss. Additional clinical trials of gildeuretinol in Stargardt disease are ongoing, including a fully-enrolled, randomized, placebo-controlled clinical trial (n = 80) in Stargardt patients with intermediate disease, expected to read out top line data in 2025. In addition, a Phase 3 study (n = 200) of gildeuretinol in patients with geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD) is now fully enrolled and is expected to read out later in 2023.

About Alkeus

Alkeus Pharmaceuticals is a biopharmaceutical company with headquarters in Cambridge, MA. Co-founded by Leonide Saad, Ph.D. and Ilyas Washington, Ph.D., Alkeus is focused on developing therapies for serious diseases of the eye with high unmet need. Alkeus' lead candidate, gildeuretinol (ALK-001), is currently being evaluated in clinical trials for the treatment of Stargardt disease and for geographic atrophy secondary to dry age-related macular degeneration (AMD). Stargardt disease is a leading monogenic cause of blindness in children and young adults.

with more than 30,000 people affected in the U.S. and more than 150,000 worldwide. Geographic atrophy is the chronic progressive degeneration of the macula in the eye, characteristic of the late stage of age-related macular degeneration (AMD), with more than one million people affected in the U.S. and more than five million worldwide.

INTERESTED IN TRANSFORMING SIGHT?

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Alkeus Pharmaceuticals, Inc.

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FDA will hold the first National Hispanic/Latino Family Cancer Awareness Week to increase cancer awareness within the Hispanic/Latino population



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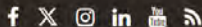
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New Drug Therapy Approvals 2022

<https://www.fda.gov/drugs/new-drug-approvals-fda/new-drug-therapy-approvals-2022>

... Expedited Development and Review Pathways Fast Track **Breakthrough Therapy** **Priority Review** **Accelerated Approval** Overall Use of Expedited Development and ...

FDA Grants Accelerated Approval for Alzheimer's Disease Treatment

<https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-disease-treatment>

Administration approved Leqembi (lecanemab-irmb) via the **Accelerated Approval** pathway for the treatment of Alzheimer's ... and Research "This treatment option is the latest **therapy** to target and affect the underlying disease process ... granted this application Fast Track , **Priority Review** and **Breakthrough Therapy** designations. The **approval** of Leqembi ...

FDA approves new type of therapy to treat advanced urothelial cancer

<https://www.fda.gov/news-events/press-announcements/fda-approves-new-type-therapy-treat-advanced-urothelial-cancer>

... Today, the U.S. Food and Drug Administration granted **accelerated approval** to Padcev (enfortumab vedotin-efv), a ... bladder and nearby organs. Padcev represents a new type of **therapy** for patients with advanced urothelial cancer whose ... The FDA granted this application **Priority Review** and **Breakthrough Therapy** designation, which expedites the ...

FDA grants accelerated approval to sotorasib for KRAS G12C mutated NSCLC

<https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-sotorasib-kras-g12c-mutated-nsclc>

... On May 28, 2021, the Food and Drug Administration granted **accelerated approval** to sotorasib (Lumakras™, Amgen, Inc.), a ... test, who have received at least one prior systemic **therapy**. FDA also approved the QIAGEN Iherascreen® KRAS RQ ... This application was granted **priority review**, fast-track, **breakthrough therapy** and orphan drug designation. A ...

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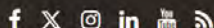
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Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review

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Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review

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Speeding the availability of drugs that treat serious diseases are in everyone's interest, especially when the drugs are the first available treatment or if the drug has advantages over existing treatments. The Food and Drug Administration has developed four distinct and successful approaches to making such drugs available as rapidly as possible:

- [Priority Review](#)
- [Breakthrough Therapy](#)
- [Accelerated Approval](#)
- [Fast Track](#)

Because each of these approaches implies speed, there can be confusion about the specific meaning of each and the distinctions among them.

Content current as of:
06/12/2023


Fast Track



Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

[Fast Track](#)


Breakthrough Therapy



A process designed to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy.

[Breakthrough Therapy](#)


Accelerated Approval



These regulations allowed drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint.

[Accelerated Approval](#)


Priority Review



A Priority Review designation means FDA's goal is to take action on an application within 6 months.

[Priority Review](#)

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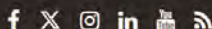
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TRANSFORMATION IN **SIGHT**



Alkeus is Addressing the Root Cause of
Stargardt Disease

Gildeuretinol
(ALK-001) has
Breakthrough Therapy
Designation



We are Building a Team to Launch
Gildeuretinol and Transform Lives

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STARGARDT DISEASE

Stargardt disease, which affects more than 30,000 people in the United States, is one of the most common genetic causes of blindness in children and young adults. No treatment exists.

WITH MORE THAN 30,000 PEOPLE IN THE U.S. STARGARDT DISEASE IS MORE COMMON THAN OTHER GENETIC DISEASES SUCH AS CF, PKU AND SMA

Of the six most common genetic, autosomal recessive diseases, Stargardt disease is the only one without a treatment.

Disease	US Patients	Incidence
Alpha-1 antitrypsin deficiency (A1AT)	~100,000	~3:10,000
Sickle cell disease (SCD)	~90,000	1:500-1,200 births
Stargardt disease* (STGD1)	>30,000	~1:8,000
Cystic fibrosis (CF)	30,000	~1:3,500 births

Phenylketonuria (PKU)	16,500	~1:16,000
Spinal muscular atrophy (SMA)	9,000	~1:8,000 births

*Reference: Worldwide carrier frequency and genetic prevalence of autosomal recessive inherited retinal diseases: 2019. Approximately 5% of the population is a carrier for an ABCA4 variant

THE ROOT CAUSE: DEFECTS IN THE ABCA4 GENE



Sight is made possible by a biochemical chain reaction in the eye: Vitamin A enables photoreceptors in the eye to convert light into electrical signals that are sent to the brain. Vitamin A is essential to the eye's ability to see but also has a propensity to form dimers — or clumps — that are toxic to retinal pigment epithelium (RPE) layer.

Mutations in the *ABCA4* gene were identified as the cause of Stargardt disease in 1997. The normal role of the ABCA4 protein is to ensure the flow of n-retinylidene-PE, a vitamin A isomer, through the photoreceptor membrane.

In Stargardt patients the ABCA4 protein is defective or absent, which allows excess vitamin A concentration and dimerization, and results in toxic by-products that irreversibly damage the RPE layer, leading to progressive vision loss.

GILDEURETINOL (ALK-001), A ONCE-A-DAY ORAL, INVESTIGATIONAL THERAPY FOR THE TREATMENT OF STARGARDT DISEASE

Gildeuretinol (ALK-001) is the first and only medicine in clinical development to selectively address the underlying mechanism of Stargardt disease, by reducing the rate of vitamin A dimerization in the eye.

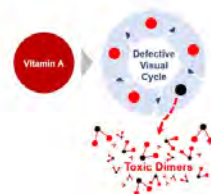
Toxic vitamin A aggregates ("dimers") have been implicated in the pathophysiology of Stargardt and dry-AMD. Gildeuretinol is a chemically-modified vitamin A and is taken once daily by mouth.

In *in vitro* studies, researchers have demonstrated that gildeuretinol slowed dimerization of vitamin A by 4-5 fold, and in *in vivo* models, gildeuretinol has reduced vitamin A dimer formation in the eye by 80%, leading to preservation of visual function in animal models of Stargardt disease.

Gildeuretinol was designed to perform all of the functions of vitamin A needed to support sight, but without the tendency to dimerize or clump, thus avoiding the toxic by-products that damage the retina. Researchers engineered gildeuretinol as a novel, selectively modified version of vitamin A, where three hydrogen atoms are replaced with deuterium atoms, a stable, non-radioactive isotope of hydrogen. This modification is what dramatically reduces the

THE PROBLEM

Vitamin A is essential for vision but forms toxic byproducts as a result of the visual cycle



THE ALK-001 SOLUTION

ALK-001 substitutes vitamin A and retains vitamin A natural functions while safely reducing the production of toxic byproducts, thereby preserving retinal health and vision. All future treatment approaches will be add-ons to ALK-001.

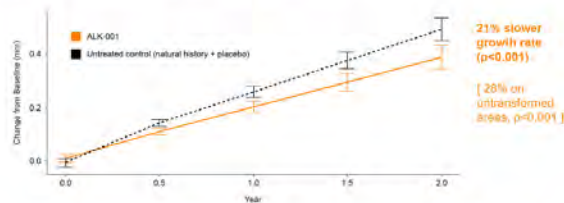


PUBLICATIONS

GILDEURETINOL CLINICAL RESULTS: A FIRST FOR STARGARDT PATIENTS

In 2022, clinical investigators reported results from a double-masked, placebo-controlled, randomized Phase 2 study of gildeuretinol (ALK-001) in 50 patients with advanced Stargardt disease at the American Academy of Ophthalmology.

GILDEURETINOL SLOWS THE GROWTH RATE OF ATROPHIC LESIONS IN STARGARDT PATIENTS



Gildeuretinol met the pre-specified primary efficacy endpoint with high statistical significance, with a consistent trend of clinical benefit seen in secondary efficacy analyses.

In the clinical trial known as TEASE-1, gildeuretinol dosed once a day resulted in decreased retinal damage as compared to placebo, based on observed growth rates in atrophic lesions as measured by fundus autofluorescence (FAF). Gildeuretinol was well-tolerated with a safety profile consistent with the well-characterized safety profile of vitamin A.

In addition, an innovative, open-label study in children, known as TEASE-3, has indicated an ability for gildeuretinol, when given early, to halt the disease process before progressive retinal damage and vision loss occurs. Results from this clinical trial are anticipated to be presented in an upcoming medical forum.

ALKEUS' CLINICAL PROGRAM WITH GILDEURETINOL IS DESIGNED TO SUPPORT BROAD USE IN STARGARDT DISEASE



References: Visual acuity loss and clinical observations in a large series of patients with Stargardt disease, 2003; Visual Acuity Change over 12 Months in the Prospective Progression of Atrophy Secondary to Stargardt disease (ProgStar) Study, 2016.

Four clinical trials of gildeuretinol in Stargardt Disease are ongoing or completed, with the first two data readouts demonstrating positive clinical efficacy data.

PURSuing A RAPID PATH TO MARKET

The U.S. FDA has granted Breakthrough Therapy Designation and Orphan Drug Designation to giledeuretinol (ALK-001) for the treatment of Stargardt disease. Alkeus is engaged in discussions with regulatory authorities to define the most appropriate path to bring giledeuretinol to Stargardt disease patients as rapidly as possible. Alkeus plans to submit an NDA for approval of giledeuretinol in Stargardt disease in 2024.

BROAD POTENTIAL TO TREAT EYE DISEASE

The pathological features of Stargardt disease—lesions in the retinal pigmental epithelium (RPE) layer, visible using high-resolution optical imaging—are common across several degenerative eye diseases.

There is mounting scientific evidence that the same process—excessive vitamin A dimerization, leading to toxic by-products that irreversibly damage photoreceptors in the retina—drives the progressive lesion growth not just in Stargardt disease but in these other diseases as well.

In addition to Stargardt disease, giledeuretinol is being evaluated in *Geographic Atrophy (GA)*, an advanced form of dry age-related macular degeneration (dry AMD). More than 1 million people in the United States and more than 5 million people worldwide have GA.



Dry AMD is common in people over the age of 50. In dry AMD, layers of the retina slowly deteriorate over time. GA may occur in later-stage dry AMD patients, and is characterized by discrete areas of damage to the RPE layer, which leads to a progressive decline in central vision.

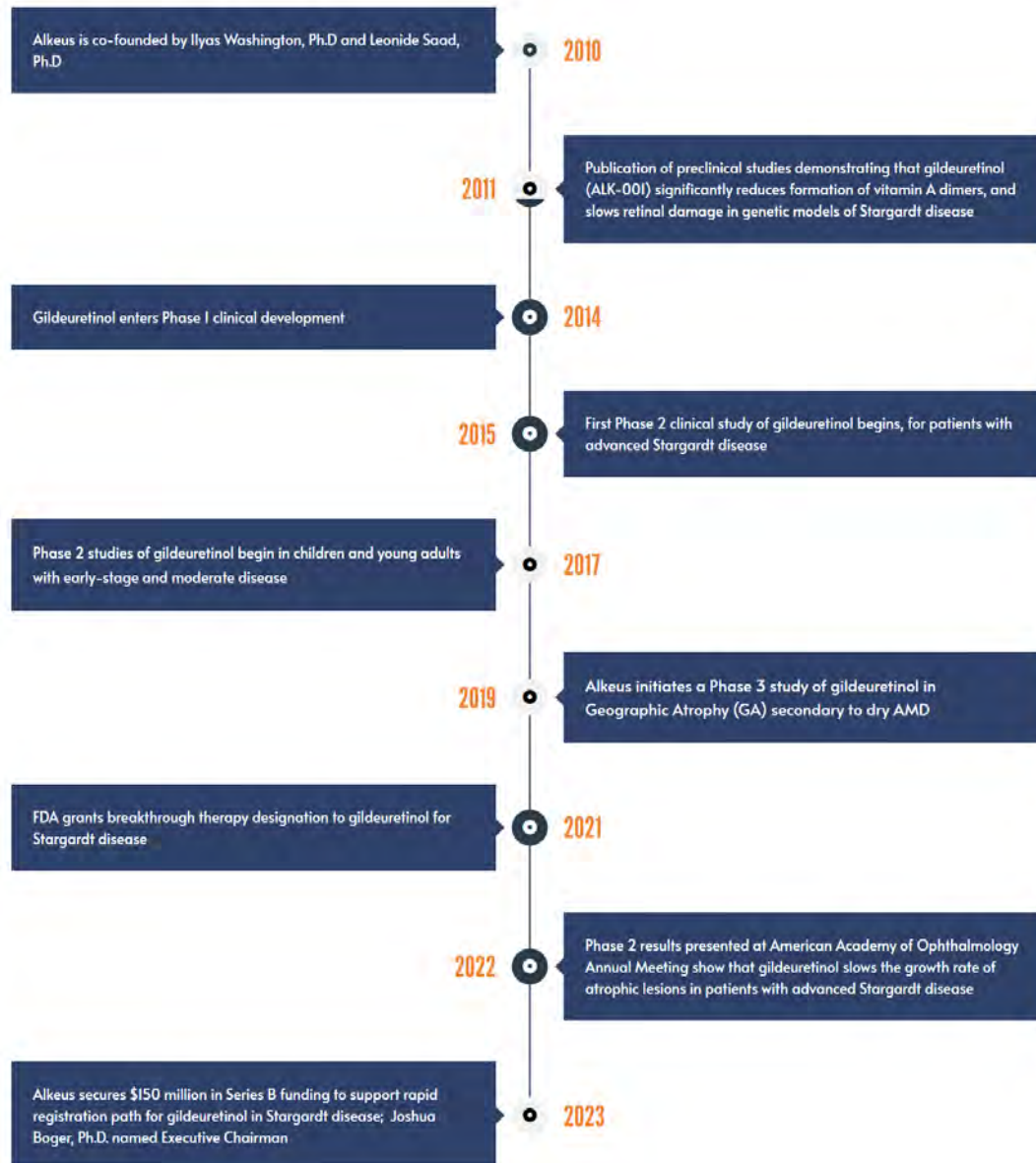
Although multiple mechanisms are associated with dry AMD and GA, it is clear that the toxic by-products of vitamin A are significant drivers of damage to the RPE layer.

In 2019, Alkeus initiated a Phase 3 study of giledeuretinol in Geographic Atrophy, with a primary goal of measuring ALK-001's ability to slow the growth rate of GA lesions. The trial is fully enrolled with 200 patients.

ABOUT ALKEUS

Alkeus was co-founded by Leonide Saad, Ph.D. and Ilyas Washington, Ph.D. with the goal of treating degenerative eye diseases in a completely new way: developing a molecule that could reduce the potential for toxicity when vitamin A dimerizes — clumps — in the eye. This dimerization is a key underlying contributor to the irreversible retinal damage that is common to a number of eye diseases.

Alkeus has steadily progressed its lead molecule gildeuretinol (ALK-001), demonstrating its tremendous promise and advancing a comprehensive clinical program.



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ALKEUS TEAM

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Board of Directors



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President and Chief Executive Officer

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Alkeus Pharmaceuticals Announces Results from the SAGA Study of Oral Gildeuretinol in Patients with Geographic Atrophy Secondary to Age-Related Macular Degeneration

September 17, 2024 | [Press Release](#)

Alkeus Pharmaceuticals Announces Presentation of a TEASE-3 Study Update Showing Progression Stalled in Early-Stage Stargardt Disease Patients Treated with Gildeuretinol

July 18, 2024 | [Press Release](#)

Alkeus Pharmaceuticals Appoints Tamara Dillon as Chief Human Resources Officer

July 16, 2024 | [Press Release](#)

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Alkeus Pharmaceuticals, Inc.

Cambridge, MA

General: info@alkeuspharma.com



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Drug Administration today announced that it has awarded **12 new clinical trial research grants** totaling more than \$18 ... from academia and industry across the country. The **FDA** awarded the **grants** through the Orphan Products Clinical ... who need them most. Three-quarters (75%) of the **new awards fund** studies enrolling children, including children as ...

FDA awards 12 grants to fund new clinical trials to advance the development of medical products for the treatment of rare diseases<https://www.fda.gov/news-events/press-announcements/fda-awards-12-grants-fund-new-clinical-trials-advance-development-medical-products-treatment-rare>

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FDA Awards 11 Grants to Clinical Trials to Develop New Medical Products for Rare Disease Treatments<https://www.fda.gov/news-events/press-announcements/fda-awards-11-grants-clinical-trials-develop-new-medical-products-rare-disease-treatments>

announced it has awarded **11 new clinical trial research grants**, equaling more than \$25 million of funding over the next four years. The **FDA's** Congressionally-funded Orphan Products **Grants** Program **awards** these **grants** to clinical investigators to support the ...

FDA awards six grants to fund new clinical trials to advance the development of medical products for the treatment of rare diseases<https://www.fda.gov/news-events/press-announcements/fda-awards-six-grants-fund-new-clinical-trials-advance-development-medical-products-treatment-rare>

that it has awarded **six new clinical trial research grants** to principal investigators from academia and industry ... "Now, more than ever, we see the important role of these **FDA grants** to support clinical trials of potentially ... products. ... Office of the Commissioner ... **FDA** announced **awards** for **six new clinical trial research grants** totaling ...

FDA awards 15 grants for clinical trials to stimulate product development for rare diseases<https://www.fda.gov/news-events/press-announcements/fda-awards-15-grants-clinical-trials-stimulate-product-development-rare-diseases>

that it has awarded **15 new clinical trial research grants** totaling more than \$22 million over the next four ... to develop medicines targeted to rare conditions," said **FDA** Commissioner Scott Gottlieb, M.D. "For more than 30 ... rare diseases. Approximately 33 percent of the **new grant awards fund** studies to accelerate cancer research by ...

FDA awards 21 grants to stimulate product development for rare diseases<https://www.fda.gov/news-events/press-announcements/fda-awards-21-grants-stimulate-product-development-rare-diseases>

that it has awarded **21 new clinical trial research grants** totaling more than \$23 million over the next four ... program," said Gayatri R. Rao, M.D., J.D., director of **FDA's** Office of Orphan Product Development, within the Office ... have little, or no, available treatment options." The **FDA awards** the **grants** through the Orphan Products Clinical Trials ...

FDA awards 18 grants to stimulate product development for rare diseases<https://www.fda.gov/news-events/press-announcements/fda-awards-18-grants-stimulate-product-development-rare-diseases>

... today announced it has awarded **18 new research grants** totaling more than \$15 million to boost the ... clinical sites domestically and internationally. "The **FDA** is in a unique position to help those who suffer from ... have little, or no, available treatment options." The **FDA awards** the **grants** through the Orphan Products **Grants** Program ...

Clinical Trial and Natural History Study Grants<https://www.fda.gov/oc/clinical-trial-and-natural-history-study-grants>

... Orphan Products **Grants** OOPD administers two Orphan Products **Grants**: Clinical ... medical products for rare diseases and conditions. The **FDA's** Office of Orphan Products Development (OOPD) **awards new** clinical trial **grants** annually. A major portion of ...

OWH Research Program Awards by Funding Year<https://www.fda.gov/oc/research/owh-funded-research/owh-research-program-awards-funding-year>

... The **FDA** Office of Women's Health (OWH) **awards** research **grants** for 1-2 year studies to address ... autophagosome-associated signaling molecules such as Atg 5-12, Atg 7, Atg 14, and Beclin 1. We further demonstrated that ...

List of OWH Research Program Awards by Funding Year<https://www.fda.gov/science-research/womens-health-research/owh-research-program-awards-funding-year>

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Orphan Grants Spotlight<https://www.fda.gov/industry/medical-devices/rare-diseases-and-conditions/orphan-grants-spotlight>

... Experts from **FDA** and the orphan products program grantees often publish ... publications as well as historical grant announcements and **awards** are below. OOPD Publications The effect of the ... of rare diseases. [ARCHIVED] October 2019 **FDA awards 12 grants to fund new** clinical trials to advance the ...

OWH-Funded Research: Pregnancy (Prevention/Exposure)<https://www.fda.gov/science-research/womens-health-research/owh-funded-research/pregnancy-prevention/exposure>

... The **FDA** Office of Women's Health (OWH) **awards** research **grants** to support **FDA** regulatory ... in Time-Pregnant Guinea Pigs. Placenta. 2015 Dec;36(12):1370-7. 2012 Applications of Clinical Pharmacology ...

MOU 225-12-0004<https://www.fda.gov/about-fda/academic-mous/mou-225-12-0004>

... The United States Food and Drug Administration (**FDA**) and Thomas Jefferson University, by and through its ... appropriations. The terms and conditions of any such **awards** will be in accordance with applicable federal law and ... an amendment to the Memorandum of Understanding (MOU) 225-12-0004 dated December 9, 2011, to change the termination ...

Communications about OOPD's Grant Programs<https://www.fda.gov/communications/about-oopd-grant-programs>

... Press releases. **FDA awards 2 grants** for natural history studies in rare diseases (October 8, 2019) **FDA awards 12 grants to fund new** clinical trials to advance the ...

FDA Roundup: September 8 2023<https://www.fda.gov/news-events/press-announcements/fda-roundup-september-8-2023>

... summary of news from around the agency. On Thursday, the **FDA's** Center for Devices and Radiological Health (CDRH) ... contact with Intact Skin. CDRH will host a webinar on Oct. 12, 2023 for industry and others interested in learning more ... medical devices for all pediatric patients." This year's **awards** include commitments to developing clinical trial ...

Rare Disease Day 2020: FDA Continues Important Work on Treatments for Rare Diseases<https://www.fda.gov/news-events/press-announcements/fda-continues-important-work-treatments-rare-diseases>

... Ph.D., Principal Deputy Commissioner. As leaders of the **FDA**, every day we see the unwavering commitment of our agency ... **Grants** Program awarded **grants** providing funding supporting **12 new** clinical trials totaling more than \$15 million over ... to innovators of medical devices for children. These **awards** include three real-world evidence projects. In 2019, ...

FDA BAA Questions & Answers<https://www.fda.gov/science-research/fda-baa-questions-answers>

... This page includes responses to questions asked at **FDA** BAA Day on December 6, 2022. For consideration in FY ... Event Materials. A recording of the full event (4 hours, 12 minutes), including closed captioning and an audio ... be posted directly to the solicitation on SAM.gov. Once **awards** are made, the award announcements will also be posted ...

FDA is Working to Bridge Gaps and Meet Needs for Rare Disease Product Development<https://www.fda.gov/news-events/press-announcements/fda-working-bridge-gaps-and-meet-needs-rare-disease-product-development>

... still do not have approved therapies. Each year, the **FDA** joins the global observance of Rare Disease Day at the ... More than \$15 million to **fund** approximately 60 ongoing and **12 new** clinical trials. Highlights of the newly funded ... to innovators of medical devices for children. Our recent **awards** included three for real-world evidence projects. ...

MOU 225-17-002<https://www.fda.gov/about-fda/academic-mous/mou-225-17-002>

... The United States Food and Drug Administration (**FDA**) and The Regents of the University of California, on ... appropriations. The terms and conditions of any such **awards** will be in accordance with applicable federal law and ... of Bioengineering and Therapeutic Sciences. September 12, 2016. Approved and Accepted for the Food and Drug ...

MOU 225-17-023<https://www.fda.gov/about-fda/academic-mous/mou-225-17-023>

... coordination with the U.S. Food and Drug Administration (**FDA**), award funds contingent upon the recipient making ... the field of RM using adult stem cells. The planned **awards** will be subject to the legal and policy obligations summarized in the NIH **Grants** Policy Statement and as otherwise specified in the ...

Accelerating Access to Critical Therapies for ALS Act – ACT for ALS<https://www.fda.gov/industry/medical-devices/rare-diseases-and-conditions/accelerating-access-critical-therapies-als-act-als>

... Services (HHS), through the Food and Drug Administration (**FDA**) and the National Institutes of Health (NIH), to ... diseases. Finally, it requires that the **FDA** award **grants** or contracts to public and private entities to cover ... neurodegenerative diseases in adults and children. These **awards** are administered by the Office of Orphan Products ...

Dr Sharpless's remarks to the 2019 NORD Conference on Rare Diseases - 10/22/2019

<https://www.fda.gov/news-events/speeches-fda-officials/dr-sharpless-remarks-2019-nord-conference-rare-diseases-10222019>

... or representatives of government agencies such as **FDA** and **NIH**. You're here today to interact, collaborate, ... 65 treatments for rare diseases. Recently, we announced **12 new** clinical trial research grant **awards** ... totaling more than \$15 million over the next 4 years ...

MOU 225-17-024

<https://www.fda.gov/about-fda/academic-mous/mou-225-17-024>

... I. Purpose The United States Food and Drug Administration (**FDA**) and the University of Washington (UW) School of Pharmacy ... Enhancing researchers' abilities to obtain and manage **grants**; Investing strategically in promising research and ... appropriations. The terms and conditions of any such **awards** will be in accordance with applicable federal law and ...

Office of Generic Drugs (OGD) Annual Report for 2017

<https://www.fda.gov/drugs/abbreviated-new-drug-application-annda/office-generic-drugs-ogd-annual-report-2017>

... approvals and tentative approvals in the history of the **FDA's** generic drug program—1,027 Issued approvals for first ... (4 th -5 th) 6 months * 60% 75% 90% Tier 2 amendments **12** months 60% 75% 90% Prior Approval Supplements 6 months * ... into 2017. GDUFA I research funding for **new** and continuing **awards** was distributed across these regulatory science ...

Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives - 10/24/2017

<https://www.fda.gov/news-events/congressional-testimony/federal-efforts-combat-opioid-crisis-status-update-cara-and-other-initiatives-10242017>

... list of HHS activities underway, SAMHSA, CDC, NIH, and **FDA** bring unique expertise and capabilities that enable HHS ... justice grantees can use up to 20 percent of their grant **awards** for the purchase of **FDA**-approved medications for ... Prescription Drug/Opioid Overdose Related Deaths to **12** states. These **grants** are also being used to train first ...

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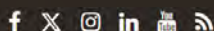
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FDA awards 12 grants to fund new clinical trials to advance the development of medical products



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<https://www.fda.gov/news-events/press-announcements/fda-awards-15-grants-clinical-trials-stimulate-product-development-rare-diseases> (/news-events/press-announcements/fda-awards-15-grants-clinical-trials-stimulate-product-development-rare-diseases)

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<https://www.fda.gov/news-events/fda-voices/rare-disease-day-2020-fda-continues-important-work-treatments-rare-diseases> (/news-events/fda-voices/rare-disease-day-2020-fda-continues-important-work-treatments-rare-diseases)

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FDA is Working to Bridge Gaps and Meet Needs for Rare Disease Product Development

<https://www.fda.gov/news-events/fda-voices/fda-working-bridge-gaps-and-meet-needs-rare-disease-product-development> (/news-events/fda-voices/fda-working-bridge-gaps-and-meet-needs-rare-disease-product-development)

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Dr Sharpless's remarks to the 2019 NORD Conference on Rare Diseases - 10/22/2019

<https://www.fda.gov/news-events/speeches-fda-officials/dr-sharpless-remarks-2019-nord-conference-rare-diseases-10222019> (/news-events/speeches-fda-officials/dr-sharpless-remarks-2019-nord-conference-rare-diseases-10222019)

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Clinical Trial and Natural History Study Grants

<https://www.fda.gov/industry/clinical-trial-and-natural-history-study-grants> (/industry/clinical-trial-and-natural-history-study-grants)

... Orphan **Products Grants** OOPD administers two Orphan **Products Grants: Clinical ... medical products** for **rare diseases** and conditions. The **FDA's** Office of Orphan **Products Development** (OOPD) **awards new clinical** trial **grants** annually. A major portion of ...

List of OWH Research Program Awards by Funding Year

<https://www.fda.gov/science-research/womens-health-research/list-owh-research-program-awards-funding-year> (/science-research/womens-health-research/list-owh-research-program-awards-funding-year)

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OWH Research Program Awards by Funding Year

<https://www.fda.gov/consumers/owh-funded-research/owh-research-program-awards-funding-year>
(/consumers/owh-funded-research/owh-research-program-awards-funding-year)

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Orphan Grants Spotlight

<https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/orphan-grants-spotlight>
(/industry/medical-products-rare-diseases-and-conditions/orphan-grants-spotlight)

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Communications about OOPD's Grant Programs

<https://www.fda.gov/communications-about-oopds-grant-programs> (/communications-about-oopds-grant-programs)

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C3TI Compass (Knowledge Repository)

<https://www.fda.gov/about-fda/cder-center-clinical-trial-innovation-c3ti/c3ti-compass-knowledge-repository>
(/about-fda/cder-center-clinical-trial-innovation-c3ti/c3ti-compass-knowledge-repository)

... the pathway for interested parties to engage with the **FDA's** mission of advancing **clinical** trial innovation. View ... is an initiative of the **Clinical** and Translational Science **Awards** (CTSA) Program. The collaborative features a single ... announcements, funding opportunity announcements, CERSI **grants**, and inter-agency agreements. This webpage lists ...

Coronavirus Disease 2019 (COVID-19)

<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19> (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)

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Section 1128 of the Food and Drug Administration Safety and Innovation Act (FDASIA): Small Business Report to Congress

<https://www.fda.gov/media/86133/download> (/media/86133/download)

... 4 **FDA** Takes an Active Role in Problem-Solving for Small ... 12 D. Access to Ombudsmen ... 23 Appendix E: **FDA Grant Awards** ... first PMA, PDP, PMR or BLA. B. Grant Programs **FDA** offers **grants** for **development** of **products** aimed at small ...

FDA's Office of Orphan Products Development (OOPD) – An Overview and Update (PDF - 1.95MB)

[https://www.fda.gov/media/147874/download \(/media/147874/download\)](https://www.fda.gov/media/147874/download)

... **FDA Drug Topics: FDA's Office of Orphan Products Development** ... research of promising therapies for **rare** disease patients **12** Office of Orphan **Products Development** (OOPD) • Established ... – Second review (external ad hoc panel of experts) – Final **awards** determined by rank ordered priority scores • ...

Speaker and Panelist Booklet FNIH-NCI-FDA Ultra-Rare Cancer Drug Development Meeting

[https://www.fda.gov/media/171559/download \(/media/171559/download\)](https://www.fda.gov/media/171559/download (/media/171559/download))

... Institutes of Health National Cancer Institute and **FDA** Oncology Center of Excellence Public Meeting on ... precision medicine, DNA repair and CTCAE. She has received **12** NIH/NCI Director **Awards** for her work in oncology. Dr. Martha Donoghue, MD is ...

Rare Disease Day 2021 Meeting Packet

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... 1 Welcome to **FDA's Rare** Disease Day 2021 Virtual Event Webcast link: ... Office of **Clinical** Policy and Programs, **FDA** 11:45am-12:45pm Lunch 12:45-1:00pm Introductory Remarks for the ... work at the **FDA** has been recognized with multiple **awards** including the Commissioner's Special Citation and the ...

January 15, 2021 - Meeting Slides Public Stakeholder Meeting on Prescription Drug Public Stakeholder Meeting on Prescription Drug Public Stakeholder Meeting on Prescription Drug Public Stakeholder Meeting on Prescription Drug Public Stakeholder Meeting on Prescription Drug

[https://www.fda.gov/media/146843/download \(/media/146843/download\)](https://www.fda.gov/media/146843/download (/media/146843/download))

... Center for Drug Evaluation and Research 4 Background ➤ **FDA** Reauthorization Act of 2017 required a public meeting and ... exchange of **medical** records between **clinical** trial sites **12** Recommendations- **Rare Diseases** ➤ Engage with **rare** disease ... On September 11, 2019 the **FDA** made the following three **awards** Migraine **Clinical** Outcome Assessment System (MiCOAS) ...

ADEPT 8 Speaker Biographies

[https://www.fda.gov/media/173725/download \(/media/173725/download\)](https://www.fda.gov/media/173725/download (/media/173725/download))

... a **clinical** pharmacologist in Canada – 2 years, Germany – **12** years and USA - 6 years. He is actively involved in the ... Pediatric Nephrology". She has received numerous teaching **awards** and community leadership recognition. Her passion ... Lead in the Office of **Clinical** Pharmacology (OCP) at the **FDA**. Her primary areas of focus are pediatrics and maternal ...

Curriculum Vitae: Nicole Hamblett

[https://www.fda.gov/media/172603/download \(/media/172603/download\)](https://www.fda.gov/media/172603/download (/media/172603/download))

... Research, Seattle Children's Research Institute HONORS, **AWARDS**, AND SCHOLARSHIPS 1990-1994 Dean's list, Santa Clara ... Department of Pediatrics 2010-2019 Tamara Simon, MD; NIH K-**12** mentoring committee member 2011-2013 Bradley Quon, MD; MPH ... NIAID Food and Drug Administration: 2005 Participant, **FDA/CFF** working group "Patient Reported Outcome Measure ...

QM COE Workshop Program Book

[https://www.fda.gov/media/177879/download \(/media/177879/download\)](https://www.fda.gov/media/177879/download (/media/177879/download))

... 1 **FDA/CDER** Virtual Workshop Streamlining Drug **Development** and ... Zhao, PhD, OGD/**FDA** 11:10 am - 11:30 am Break 11:30 am - 12:40 pm Needs, Gaps, and Opportunities in Quantitative ... exceptional

contributions were recognized with prestigious **awards**, including the **FDA's** Outstanding Achievement Award and ...