APL-2 May Soon Become the First Treatment for Dry AMD

Apellis Pharmaceuticals has announced long term results from their Phase 3 DERBY and OAKS clinical studies, testing the efficacy and safety of APL-2 (now called intravitreal pegcetacoplan), as a treatment for geographic atrophy (GA).

GA is also known as advanced dry age-related macular degeneration. In an analysis conducted at month 18 of the clinical studies, treatment with both monthly and every-other-month pegcetacoplan reduced GA lesion growth as compared to sham injections (no treatment). Pegcetacoplan continued to demonstrate a favorable safety profile in both studies.

Overall, these longer-term results provide further evidence that pegcetacoplan meaningfully slows disease progression and has the potential to preserve vision longer. Apellis remains on track to submit a New Drug Application to the U.S. Food and Drug Administration in 2022.

According to SriniVas Sadda, M.D., President & Chief Scientific Officer of the Doheny Eye Institute and lead investigator, “This study provides exciting evidence to support further exploration of the potential of pegcetacoplan for earlier intervention in the course of GA.”
A Note from Liz

New Video Interviews

We are excited about this year’s American Academy of Ophthalmology (AAO) annual meeting in Chicago. We are set to record interviews with some of the top researchers and low vision specialists in the field.

Among many others, we will learn from David Boyer, MD about photobiomodulation (PBM) treatment for Dry AMD.

Mehta Mitul, MD and Augmented Reality smart glasses

Susanna Park, MD will tell us about Stem Cell Therapy for retinal disease.

Divya Rao, MD will discuss a deep-learning automated screening tool designed to be deployed with a smartphone.

Yannis Mantas Paulus MD will be talking about Clinical Validation of a Handheld Device for Remote Monitoring of Dry Macular Degeneration.

So stay alert and count on the Macular Degeneration Foundation to publishing the latest news here, in our Magnifier Newsletter, and on our website as timely Reports at Eyesight.org.

This was a very distinguished honor for one of the most dedicated professionals in the field of eye care. Dr. Fontonnet has three not-for-profit low-vision clinics in and around Alabama. His passion for providing low-vision care has been an inspiration to us and to everyone in the low-vision community.

Liz Trauernicht - Pres
The Importance of Omega-3

Studies have shown that consuming omega-3 fatty acids, whether in foods you eat or in a supplement, may help reduce your risk of developing macular degeneration and glaucoma.

Omega-3 fatty acids can’t be made by the body naturally, so you may not be getting what you need to stay healthy if you’re not eating the right foods. At least 2 servings a week of cold-water fish such as salmon, trout, or tuna will provide the recommended source of omega-3. A serving is considered 3-4 ounces. Oysters, sardines and anchovies are also good sources of this fatty acid.

If you’re not a seafood lover, some plant sources, such as nuts and seeds, contain ALA, another type of omega-3 that’s also good for you. ALA can be found in walnuts, chia seeds, flaxseed, canola oil, soy and tofu.

Other foods that contain smaller amounts of fatty acids are eggs, meats and dairy products from grass-fed animals. Hemp seeds, spinach and Brussels sprouts also contain some omega-3s.

Consider Putting Grapefruit on Your Shopping List

In the event you haven’t had one recently, here’s a reminder to pick up a Grapefruit the next time you’re shopping for something that is both sweet and tart.

Grapefruit are rich in nutrients, antioxidants, and fiber. This makes them one of the healthiest citrus fruits you can eat.

Research shows that grapefruit may also have some powerful health benefits. These benefits include weight loss, a reduced risk of heart disease, and protection for your immune system.

On the other hand, some medications don’t mix well with grapefruit. To avoid any adverse reaction, make sure to check with your doctor or pharmacist first.
Samsara Vision Announces 2nd Generation Implantable Miniature Telescope

In 2010 a unique device called the Implantable Miniature Telescope (IMT) was FDA approved for low-vision patients that were candidates for this procedure. The device was described as a miro-sized precision telescope providing magnification of up to 3 times and a 20° field of view. It is implanted in one eye in an outpatient surgical procedure conducted under local anesthesia. It has since been implanted in more than 600 patients affected by late-stage age-related macular degeneration (AMD).

An improved version of the IMT is now offered by Samsara Vision under the brand name SING IMTTM (Smaller-Incision New-Generation Implantable Miniature Telescope). The new technology is essentially the same as the first generation IMT, in which the tiny telescope is implanted through an incision in the cornea. An important difference, however, is that it can be folded for pre-loading into a special delivery system enabling a smaller corneal incision and safer less complicated surgery.

The SING IMTTM is already approved in several countries, but not yet in the United States. Toward that end, Samsara has announced FDA approval to initiate a U.S.-based study to evaluate improvements in visual acuity and to ensure safety of the device in people living with late-stage age-related macular degeneration.
CONCERTO Trial Seeking Participants

The CONCERTO trial is now recruiting older adults living with non-active neovascularization (blood vessel growth), central blind spots in both eyes, and geographic atrophy or scarring of the fovea (the center of the macula). Participants will receive a SING IMTMM in one eye. They must be aged 65 or older, cannot have had previous cataract surgery in the study eye, and must agree to post-operative rehabilitation and training. Both the operative and the non-study eye will be assessed pre- and post-operatively across five visits over 12 months. The CONCERTO trial will take place in up to twenty U.S. clinical sites including California, Florida, Massachusetts, New Jersey, Pennsylvania, Wisconsin. Follow this link for complete details about the trial and locations.

The SING IMTMM is not a cure for late-stage dry (geographic) AMD. It will not return vision to the level a patient had before AMD, nor will it completely make up for vision loss. The technology, however, has been shown to significantly improve vision and quality of life for individuals with this incurable disease.

To learn more about the study and inquire about participation, visit www.concertostudy.com

Practice the 20-20-20 Rule

Here are some sight-saving tips to prevent blue light damage caused by too much time in front of screens. Blue light that is emitted from digital screens can cause eye strain and put people at greater risk for macular degeneration. So, what can you do to protect your sight?

First, move farther away from your screen. By moving two feet from the screen you can reduce exposure by 25%. Another effective strategy to limit digital eye strain is to follow the 20-20-20 rule, which is for every 20 minutes behind a screen, take a 20-second break and look at something 20 feet away.
BYOOVIZ™ Launches in the U.S.

Biogen Inc. and Samsung Bioepis Co., Ltd. has announced that BYOOVIZ™ (ranibizumab-nuna), a biosimilar of LUCENTIS® (ranibizumab) has been launched in the U.S. The list price will be $1,130 per injection, which is 40% lower than the current list price of LUCENTIS.

The FDA approved BYOOVIZ in September 2021 for the treatment of neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion, and myopic choroidal neovascularization.

Neovascular (wet) AMD, although less common than dry AMD, is responsible for the majority of the severe vision loss or blindness associated with AMD. Anti-VEGF therapies have become a standard of care treatment for wet AMD. Biosimilars, which are biologics with similar efficacy and comparable safety to reference biologics, have the potential to alleviate the financial burden associated with current anti-VEGF therapies.

“The launch of BYOOVIZ in the U.S. marks an important moment for patients, healthcare providers, payers, and the entire healthcare system. Patients [with] retinal vascular disorders now have a more affordable treatment option,” said Ian Henshaw, Senior Vice President and Global Head of Biosimilars at Biogen.

BYOOVIZ is the first biosimilar launch in the U.S. under the Biogen and Samsung Bioepis’ partnership. In addition to the U.S., BYOOVIZ was also approved as the first ophthalmology biosimilar in Europe (2021), the United Kingdom (2021), and Canada (2022).
Exclusive Online Videos Featuring World’s Leading Eye Researchers

The Macular Degeneration Foundation interviews the world’s foremost scientists, medical practitioners and inventors. Visit Eyesight.org for the latest news and register to receive an email notice when new videos are first posted.

Donations Appreciated

The Macular Degeneration Foundation, Inc. is a tax-exempt, non-profit organization.

Please visit our website at eyesight.org to make a tax deductible donation.

Checks may be mailed to:

Macular Degeneration Foundation, Inc.,
P.O. Box 531313,
Henderson, NV 89053

Call: 888-633-3937 (USA)
Call: 702-450-2908 (Intl)
Email: liz@eyesight.org

Disclaimer - Articles in the Magnifier are for information only and are not an endorsement by the Macular Degeneration Foundation editorial staff.
Stealth BioTherapeutics Completes Treatment of Final Patient in Phase 1 Clinical Trial

According to the company, it is developing elamipretide for treatment of extra-foveal GA under U.S. FDA Fast Track designation.

A deficit in vision under low light conditions, such as at dusk, during nighttime, or with artificial lighting, is often the first clinical symptom of dry AMD. Elamipretide previously demonstrated improvement from baseline in assessments of low-light visual function and a lower-than-expected rate of GA progression (relative to the natural history) after 24-weeks of elamipretide therapy in ReCLAIM, a Phase 1 clinical trial that enrolled 40 subjects with dry AMD.

Stay tuned for more information on these treatment trials.