Statistically Significant Slowing of Disease Progression

By Dan Roberts - MD Foundation Resource Director

APL-2 is a synthetic peptide which shuts down the complement activation system responsible for local inflammation, tissue damage (as in dry AMD) and the resulting blood vessel growth (angiogenesis in wet AMD).

Discovered by Professor John Lambris, University of Pennsylvania, APL-2 (formerly called POT-4) was the first complement inhibitor tested in patients with dry AMD, also called “geographic atrophy”. On Feb. 10, 2015, Apellis Pharmaceuticals announced the beginning of Phase I clinical trial of APL-2. The multi-center trials, labeled ASAP II, focused on establishing safety of intravitreal injections of APL-2.

After success at that stage in 2015, Apellis began a larger Phase II trial. Now the company reports that APL-2 has demonstrated a statistically significant slowing of geographic atrophy over 12 months, while appearing to increase in the second 6 months of the study. This represents a slowing of the rate of degeneration by almost half, according to Apellis founder and CEO Cedric Francois, MD, PhD. Plans are underway to move forward with Phase III.
FDA Issues Warning To Stem Cell Clinics

On August 28, 2017, the U.S. Food and Drug Administration posted a warning letter issued to US Stem Cell Clinic of Sunrise, Florida, and its Chief Scientific Officer Kristin Comella for marketing stem cell products without FDA approval and for significant deviations from current good manufacturing practice requirements, including some that could impact the sterility of their products, putting patients at risk.

“Stem cell clinics that mislead vulnerable patients into believing they are being given safe, effective treatments that are in full compliance with the law are dangerously exploiting consumers and putting their health at risk,” said FDA Commissioner Scott Gottlieb, M.D. “As the FDA takes new steps to advance an efficient, modern approach to the regulation of cell based regenerative medicine, at the same time we will be stepping up our enforcement actions against clinics that abuse the trust of patients and, more important, endanger their health with unsanitary conditions or by purporting to have treatments which may not provide any benefit.”

A Letter from Liz

Liz Traurnicht - Pres MD Foundation

Dr. Alan Marmorstein, in an exclusive MDF video, discusses requirements and proper procedures for clinical trials (MacularNews.org)
AIRA: A Breath of Fresh Air

Aira is Italian for air. In the low vision field, AIRA is a new device helping the blind and visually impaired. Originally designed and patented by Dr. Edward Yavitz, an ophthalmologist in Loves Park, Illinois, it is now being produced and marketed by AiraIO in San Diego, California.

Aira is a very small, lightweight glass frame mounted video camera connected to the internet wirelessly by a small transmitter and a free cell phone app.

It is monitored live by people who are trained to assist the blind and visually impaired and called “agents”. Information and instructions are relayed real-time to the person wearing the device, and questions may be asked and answered.

Continued ...
Are You Missing Out on Benefits?

April Issue of AARP by Joan Rattner Hellman

If you’re struggling to pay for health care, food, or utilities, help may be closer than you realize.

Older Americans miss out on more than $20 billion worth of benefits every year. A nationwide campaign launched by the National Council on Aging and the National Association of Area Agencies on Aging aims to help older adults learn about two easily accessed resources that can connect them to needed support.

BenefitsCheckUp (benefitscheckup.org)

Eldercare Locator (1-800-677-1116 or eldercare.gov)

Continued ... “AIRA: A Breath of Fresh Air”

A totally blind or severely impaired person may receive instructions and directions while traveling, shopping or performing any number of activities. Signs and printed material can be read by the “agent”. This device will allow the visually impaired to perform activities and travel in ways not previously possible.

This service has the potential for adding optical character recognition and other features and, as it is online, could be applied without returning the camera. Updates could be done automatically without the need to obtain a new unit.

The way Aira is being marketed is indeed a breath of fresh air in the field of head-mounted technology for the blind and visually impaired. Commonly, devices have been very expensive up-front, and usually non-returnable. Aira is leased, not purchased, and is available for the first month as a trial with the initial fee of $89. If not helpful for your particular needs, it may be returned without penalty.

This is a dramatic change from the usual marketing and pricing strategy for such devices. Dr. Yavitz and Mr. Troy Otillo, CEO of ARIA, are to be commended for a humane and sincere effort to help the visually impaired. They are indeed a breath of fresh air.

To contact Aira: Go to their web site: www.aira.io

Joe Fontenot MD, CLVT
Community Services for Vision Rehabilitation
Mobile AL
All Avenues Need To Be Considered For Improving Vision

By Dan Roberts - MD Foundation Resource Director

A paper soon to be published in The Lancet (Volume 5, No. 9, e888–e897, September 2017) estimates that in 2015, 36 million people in the world were blind and 217 million people were severely or moderately vision impaired. It also estimated that 1.1 billion people aged 35 years and older had near-vision impairment due to uncorrected presbyopia.

Presbyopia is when your eyes gradually lose the ability to see things clearly up close. It is a normal part of aging. The paper, published by the Vision Loss Expert Group, is part of an extensive initiative called Universal Eye Health: a Global Action Plan 2014–2019, which was adopted in 2013 by the World Health Organization. Their report shows that cataracts and presbyopia are the most prevalent vision-robbing conditions in the older population.

The good news is that both of these impairments are correctable. Presbyopia can be corrected with reading glasses, and vision loss from dense cataracts can be corrected with surgical replacement of the lens. Furthermore, presbyopia can also be corrected during cataract surgery by implanting a multifocal lens.

Why is this important information for people affected by retinal degenerative diseases? Here is a case in point: Eleanor, a 95-year-old woman with early-stage age-related macular degeneration (AMD), blames her retinal condition for her inability to read normal print. She knows that AMD is incurable and progressive, and that she has no cataracts, but she is unaware that she also has presbyopia. She has simply given up trying to read, not realizing that she might be able to solve her problem by simply donning inexpensive reading glasses and increasing the light.

Eleanor and others in her situation need to be reminded that their visual acuity can be affected by conditions secondary to AMD, and that all avenues need to be explored in order to help maintain their quality of life. This becomes the duty of their eye care professionals, rehabilitation specialists, and caregivers. The Global Action Plan’s goals are “to reduce vision impairment as a global public health problem and to secure access to rehabilitation for people with vision impairment”. The initiative has the target of reducing the prevalence of avoidable vision impairment by 25% from 2010 to 2019. Public education about their findings is an important part of furthering their admirable mission.
New App for iOS Reads Text and Describes the World

Microsoft has released a free app using new technology to assist blind people. It’s called Seeing AI: Talking Camera for the Blind and is only available for iOS devices at this time.

The app harnesses the power of Artificial Intelligence (AI) to narrate the world around the user by describing nearby people, text and objects. Once it is downloaded, the user simply points the device’s camera at another person and it will describe them.

Seeing AI can also read text aloud that appears on the screen. It can help someone who is visually impaired listen to text from a book, find grocery items on the store shelf, and much more. The app is optimized for use with VoiceOver and helps to recognize:

**People**
Stores people’s faces so you can recognize them later. The app gives an estimate of their age, gender and emotions.

**Short text**
Speaks text as soon as it appears in front of the camera.

**Documents**
Gives audio guidance to capture a printed page for reading by VoiceOver.

**Products**
Lets the user scan barcodes with the assistance of audio beeps to guide them. The name of the product as well as package information can be heard.

**Scenes**
Speaks an overall description of the user’s surroundings.

**Images in other apps**
Tap “Share” and “Recognize” with Seeing AI to hear descriptions of images from mail, photos, social media apps, and more.

Seeing AI uses technology similar to self-driving cars and drones. Most of the app’s functions are executed right on the user’s gadget, but some of the more elaborate ones need a connection to the cloud.
Dr. David Seftel, Director of Research Development for the Macular Degeneration Foundation, interviews the world’s foremost scientists and medical practitioners. Visit MacularNews.org for the latest news and register to receive an email notice when new videos are first posted.

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Call: 702-450-2908 (Intl)
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Disclaimer - Articles in the Magnifier are for information only and are not an endorsement by the Macular Degeneration Foundation editorial staff.
Lampalizumab for Dry AMD
Unable to Meet Expectations

Genentech has announced that the primary endpoint has not been met in Spectri, the first of two Phase III studies evaluating the safety and efficacy of lampalizumab. Lampalizumab, as reported in our last issue, is an investigational medicine for the treatment of geographic atrophy (GA) due to age-related macular degeneration (AMD). It was designed to inhibit Complement Factor D, a protein best known for its role in reducing inflammation.

Further dosing in patients will be interrupted until the results from a second Phase III study are evaluated. “While this result is disappointing, we will continue to evaluate results from Spectri to get a clearer understanding of the data as we await the results of our second Phase III study, Chroma, anticipated in November.”