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COMBINATION THERAPY SHOWS NO BENEFIT OVER AFLIBERCEPT ALONE IN PHASE 2 AMD TRIAL

The phase 2 CAPELLA study evaluating aflibercept (Eylea, Regeneron) coformulated with rinucumab (Regeneron), an anti–platelet-derived growth factor (anti-PDGF) receptor beta antibody, in patients with neovascular age-related macular degeneration (AMD) failed to reach its primary endpoint, according to a company press release.

At 12 weeks, the combination therapy did not demonstrate an improvement in BCVA compared with aflibercept monotherapy. The press release reported that patients in the combination therapy arms showed a 5.8-letter improvement in BCVA, compared with a 7.5-letter improvement in the monotherapy arm.

The CAPELLA trial is an ongoing phase 2 double-masked, randomized, controlled, multiple-dose, regimen-ranging study that has enrolled approximately 500 patients with wet AMD. Researchers randomly assigned patients to one of three groups: Patients received fixed doses every 4 weeks of 2 mg aflibercept monotherapy, 2 mg aflibercept/1 mg rinucumab combination therapy, or 2 mg aflibercept/3 mg rinucumab combination therapy. At week 12, two of the three treatment groups were rerandomized, resulting in five total dosing groups in the second phase of the study. Researchers will again evaluate data at weeks 28 and 52.

The company reported that combination therapy showed no benefit over monotherapy on anatomic endpoints including reduction in retinal thickness or resolution of subretinal hyperreflective material. Ocular adverse events at week 12 were more common in the combination therapy groups (23.5% and 20%) than in the monotherapy group (16%), according to the company.

VISUAL 1 Study: Adalimumab Associated with Uveitis Improvements

In patients with uveitis, adalimumab (Humira, AbbVie) was associated with lower risk of uveitic flare or visual impairment compared with placebo, according to a study published in the *New England Journal of Medicine*.[1]

VISUAL 1 was a multinational phase 3 trial in which patients with active noninfectious intermediate uveitis, posterior uveitis, or panuveitis despite having received prednisone treatment for 2 or more weeks were randomly assigned in a 1:1 ratio to receive adalimumab or placebo. All patients received a mandatory prednisone burst followed by tapering of prednisone over the course of 15 weeks.

The median time to treatment failure was 24 weeks in the adalimumab group, compared with 13 weeks in the placebo group. Patients who received adalimumab were significantly less likely than those in the placebo group to experience treatment failure. The treatment group also showed significantly better changes in anterior chamber cell grade, vitreous haze grade, and BCVA compared with the placebo group. There were more adverse events and serious adverse events reported in the treatment group than in the placebo group.

1. Jaffe GJ, Dick AD, Brezin AP, et al. Adalimumab in patients with active noninfectious uveitis [published online ahead of print September 8, 2016]. *N Engl J Med*.

Study: Link Between Cataract Surgery and AMD Uncertain in Asian Eye Study

Researchers found no link between cataract surgery and development or progression of AMD in a population study in Asian eyes, except for an increased risk for AMD development in left eyes that may have been a chance finding, according to a study published in *JAMA Ophthalmology*.[1]

The researchers in this cross-sectional study used a multistage, probability-cluster survey sample to produce nationally representative estimates from 20,419 participants in the Korea National Health and Nutrition Examination Survey. Data from 2008 to 2012 on cataract status and AMD grade were analyzed.

Data from 34,869 eyes were analyzed; right eyes and left

eyes had cataract surgery at equal rates. Of the 1,056 right eyes and the 949 left eyes with any AMD, 167 right eyes (15.2%) and 147 left eyes (13.7%) had cataract surgery.

The analysis did not show any association between cataract surgery and AMD in right eyes but did show that left eyes that underwent cataract surgery were more than twice as likely to develop AMD. However, the authors wrote that the finding for left eyes may have been a chance finding, and they said that "the results suggest that the association between cataract surgery and AMD is uncertain in the current era of phacoemulsification."

1. Park SJ, Lee JH, Ahn S, Park KH. Cataract surgery and age-related macular degeneration in the 2008-2012 Korea National Health and Nutrition Examination Survey. *JAMA Ophthalmol*. 2016;134:621-626.

Genes Linked to Eye Color Carry Risk for Uveal Melanoma

Certain inherited genetic factors associated with eye and skin pigmentation are associated with increased risk for developing uveal melanoma, a study published in *Scientific Reports* has found.[1] This is the first study to provide evidence that "genetic factors associated with pigmentation traits are risk loci of [uveal melanoma] susceptibility," the authors said. An estimated 2,500 US adults are diagnosed with uveal melanoma each year.[2]

Researchers took samples from more than 270 patients with uveal melanoma and analyzed 28 inherited genetic mutations previously known to be linked with skin melanoma through genome-wide association studies. They found that five of the 28 mutations were significantly associated with uveal melanoma risk and that the three most significant genetic associations occurred in a genetic region that determines eye color.

1. Ferguson R, Vogelsang M, Ucisik-Akkaya E, et al. Genetic markers of pigmentation are novel risk loci for uveal melanoma [published online ahead of print August 8, 2016]. *Sci Rep*.
2. Ocular Melanoma Foundation. About ocular melanoma. www.ocularmelanoma.org/disease.htm. Accessed September 29, 2016.

B + L Releases New 27-gauge Instruments

Bausch + Lomb announced this week the release of a 27-gauge diamond dusted membrane scraper and a 27-gauge directional laser probe. The company said that its 27-gauge diamond dusted membrane scraper in the first of its kind.

The 27-gauge scraper features a diamond dusted silicone tip designed to atraumatically facilitate the peeling of internal limiting membranes or epiretinal membranes during macular hole or macular pucker surgery.

The 27-gauge directional laser probe passes in and out of the cannula in a straight formation. The straight format reduces the risk of bumping the natural lens when the device enters the eye, according to the company, and it provides the ability to work around the posterior pole when applying laser treatment. The probe can move from straight to curved at 85° without actuating the fiber toward the retina, the company said. The probe is compatible with most modern retinal lasers, the company said.

Two New Photocoagulators Enter the Market

In September, Quantel Medical launched the Easyret fully integrated 577-nm yellow photocoagulator for macular and peripheral retinal pathologies.

According to the company, the Easyret has a broad range of settings for treatment of pathologies including diabetic retinopathy, macular edema, and central serous chorioretinopathy.

Surgeons can choose between single-spot treatment mode, multispot mode for a pattern of simultaneous targets, or subthreshold micropulse mode, which allows customization of a train of short pulses to precisely manage the thermal effect on targeted tissues.

Also in September, the US Food and Drug Administration issued 510(k) clearance to Nidek for its GYC-500/GYC-500 Vixi Green Scan Laser Photocoagulator, making it available in the United States.

The GYC-500/GYC-500 Vixi is a solid state green laser that achieves stable treatment outcomes for multiple applications including retinal photocoagulation, Nidek stated. The photocoagulator has 22 preprogrammed scan patterns to allow treatment of varying retinal pathologies.

NIH Grant Awarded to Advance Research on Blindness Caused by Genetic Disorders and Aging

Indiana University (IU) received a $1.9 million grant from the National Institutes of Health's National Eye Institute to advance basic research on the eye with applications for blindness caused by genetic disorders and aging.

The 5-year award to Andrew Zelhof, PhD, an associate professor in the IU Bloomington College of Arts and Sciences' Department of Biology, will support his investigation of the effects of both congenital birth defects and age on the eye using insects as model species. Early-stage research will focus on studying cellular and molecular mechanisms in the eyes of *Drosophila melanogaster*. Previous research by Dr. Zelholf indicated that the protein prominin-1 plays a role in the development of fruit fly photoreceptors; this finding could potentially lead to applications for the treatment of prominin-induced human retinal degeneration and autosomal recessive retinitis pigmentosa. ■