

POSITIVE RESULTS WITH BISPECIFIC ANTIBODY FOR DME

Patients with diabetic macular edema (DME) treated with a novel bispecific antibody (RG7716; Genentech) showed clinically meaningful and statistically significant improvements in visual acuity gains compared with patients receiving ranibizumab (Lucentis; Genentech), according to results of a phase 2 study.¹ Top line results of the study, BOULEVARD, were presented by Pravin U. Dugel, MD, at Angiogenesis, Exudation, and Degeneration 2018.

RG7716 is a bispecific monoclonal antibody that binds simultaneously to VEGF-A and angiopoietin-2 (Ang-2). Ang-2 is a cytokine that is

upregulated in certain disease states and that, working in concert with VEGF increases inflammation and vascular permeability. The BOULEVARD phase 2 study assessed two doses of RG7716, 1.5 mg and 6 mg, in comparison with ranibizumab 0.3 mg in monthly intravitreal injections. The study met its primary endpoint, demonstrating a significant improvement in adjusted best corrected visual acuity at 24 weeks for RG7716 compared with ranibizumab in treatment-naïve patients. In a secondary endpoint assessing anatomic response, patients in both RG7716 arms had greater mean reduction in central retinal

thickness and greater improvements in diabetic retinopathy severity score. The drug was well tolerated with no new safety signals observed.

Study enrollment in BOULEVARD is completed, and Genentech plans to discuss phase 3 studies with the US Food and Drug Administration (FDA) once data assessment is complete. The same drug, RG7716, is also being assessed for the treatment of neovascular age-related macular degeneration (AMD) in the phase 2 AVENUE and STAIRWAY studies.

1. Dugel PU. Anti-VEGF/anti-angiopoietin-2 bispecific antibody rg7716 in diabetic macular edema: results from the phase 2 BOULEVARD clinical trial. Paper presented at: Angiogenesis, Exudation and Degeneration 2018. February 10, 2018; Miami, FL.



STATIN USE MAY CONFER SOME BENEFIT IN DETACHMENT SURGERY

Patients taking a statin at the time of primary vitrectomy for retinal detachment (RD) had a lower risk of reoperation than those not taking a statin, according to a registry-based cohort study in Finland.¹ Use of a statin was associated with a 28% lower risk of revitrectomy in patients undergoing surgery for rhegmatogenous RD, the study authors reported.

The researchers analyzed records for more than 5700 patients operated on at a tertiary academic hospital in Finland from 2008 to 2014. The primary endpoint was

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reoperation within 1 year of primary vitrectomy. Subgroup analyses were performed for patients undergoing vitrectomy for rhegmatogenous RD, macular pucker or hole, diabetic maculopathy or proliferative retinopathy, vitreous hemorrhage, lens subluxation, vitreous opacities, and other indications. Rhegmatogenous RD was the second most common indication for vitrectomy, including 1916 patients with 305 reoperations, a rate of 0.2 per person-year. No association between statin use and vitrectomy outcome was seen for the other surgical subgroups.

This research group has previously reported improved outcomes after primary vitrectomy in patients taking statins; they theorized that statin medications reduce inflammatory response in the eye.²

1. Loukovaara S, Sahanne S, Takala A, Haukka J. Statin use and vitreoretinal surgery: Findings from a Finnish population-based cohort study [published online ahead of print January 16, 2018]. *Acta Ophthalmol*.

2. Tuuminen R, Sahanne S, Haukka J, Loukovaara S. Improved outcome after primary vitrectomy in diabetic patients treated with statins. *Eur J Ophthalmol*. 2016;26(2):174-181.

OCT SYSTEM IMAGES ENTIRE EYE

An optical coherence tomography (OCT) device that incorporates an electronically tunable lens (ETL) technology is capable of imaging both the anterior and posterior segments, an international group of researchers reported.¹

The device uses a swept source platform and the ETL to provide sequential 3-D in vivo imaging of the anterior and posterior segments, according to the researchers. The device can also perform quantitative optical biometry.

Because of the refractive properties of the eye, standard OCT devices have been limited to either anterior segment or posterior segment imaging. The adaptive properties of the ETL allow this device to focus on the retina or the anterior segment. Further, the ability to dynamically control the ETL's focus permits enhancement of the images generated, the authors stated,

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providing unprecedented detail in imaging the vitreoretinal and vitreolenticular interfaces.

The device is still in laboratory prototype phase, according to a press release from the Optical Society, the organization that publishes the journal in which the paper is published. To bring the technology to the clinic, the researchers are now focused on optimizing the scan areas and developing processing tools to automatically measure the dimensions of the eye.

1. Grulkowski I, Manzanera S, Cwiklinski L, Sobczuk F, Karnowski K, Artal P. Swept source optical coherence tomography and tunable lens technology for comprehensive imaging and biometry of the whole eye. *Optica*. 2018;5(1):52-59.

FUND WILL SEEK TO HELP PATIENTS WITH IRDs

The Assistance Fund, a charitable patient-assistance foundation that helps patients facing high out-of-pocket medical costs, has launched a program to support individuals with inherited retinal diseases (IRDs). The fund will help patients pay medical costs associated with treatments for these rare conditions, the Assistance Fund announced in a press release.

The assistance is timely, as the first gene therapy treatment for an IRD was approved by the FDA in December, and analysts have predicted that the cost of the therapy may be as high as \$1 million for a patient's two eyes.

IRDs are caused by gene mutations that affect the retina. Approximately

200,000 individuals in the United States have an IRD, with the largest percentage, 40%, affected by retinitis pigmentosa.

The Assistance Fund manages more than 30 funds, each of which covers FDA-approved medications that treat a specific disease, according to the press release.

OPHTHALMIC CAROTUXIMAB SHOWS SIGNS OF ACTIVITY IN REFRACTORY AMD

A novel ophthalmic formulation of carotuximab (DE-122; Santen) showed signs of activity and was associated with no serious adverse effects in a phase 1/2 study in patients with refractory AMD. Top line results of

the study were presented by Victor H. Gonzalez, MD, at Angiogenesis, Exudation, and Degeneration 2018.¹

An open-label, dose-escalation, sequential-cohort phase 1/2 study assessed the safety, tolerability, and bioactivity of a single intravitreal injection of DE-122 at four dose levels. Twelve patients with wet AMD that was refractory to VEGF inhibition received ascending doses (three patients per dose level). Patients were then followed for 90 days. The signs of bioactivity in the study were based on observations of mean change in central subfield thickness on OCT.

Carotuximab is a chimeric monoclonal antibody. It is marketed for the treatment of cancer as TRC105 by Tracoon Pharmaceuticals. DE-122 is a novel ophthalmic formulation of carotuximab that has demonstrated activity in preclinical models of

choroidal neovascularization and is expected to enhance the effect of anti-VEGF agents in the treatment of wet AMD, according to Santen.

1. Gonzalez VH. Phase I/II study: safety and bioactivity of carotuximab (DE-122) for refractory wet age-related macular degeneration. Paper presented at: Angiogenesis, Exudation and Degeneration 2018. February 10, 2018; Miami, FL.

BRIEFS

> TYPE 1 DIABETES RESEARCH EFFORT LAUNCHED

The Juvenile Diabetes Research Foundation and The Mary Tyler Moore & S. Robert Levine, MD, Charitable Foundation have announced a new research effort will bring together international leaders in basic and clinical research to brainstorm disruptive and paradigm-shifting approaches with the potential to reverse type 1 diabetes-related blindness.

bit.ly/Brief318a

>> ALGORITHM COULD IMPROVE DIAGNOSIS OF RETINAL DISEASE

A new algorithm for optical coherence tomography equipment has demonstrated the ability to automatically segment images of the retina into seven layers. The technique could improve the accuracy and speed of identifying and diagnosing damage to the retina.

bit.ly/Brief318b

>>> ENROLLMENT IN PHASE 2B TRIAL FOR DR COMPLETE

Aerpio Pharmaceuticals has completed patient enrollment in its TIME-2b study designed to assess the safety and efficacy of AKB-9778, a Tie2 inhibitor, for patients with moderate to severe nonproliferative diabetic retinopathy (DR).

bit.ly/Brief318c