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FDA Approved Aflibercept for Diabetic Retinopathy in Presence of Diabetic Macular Edema

The US Food and Drug Administration (FDA) has approved aflibercept (Eylea, Regeneron) for the treatment of diabetic retinopathy (DR) in patients with diabetic macular edema (DME), according to a press release. The approval is for a 2.0 mg dosage, administered every 8 weeks following five initial monthly loading doses.

The FDA relied on data from the phase 3 VISTA and VIVID trials. The trials compared aflibercept 2.0 mg every 4 weeks, aflibercept 2.0 mg every 8 weeks following five initial monthly loading doses, and macular laser photocoagulation (at baseline and then as needed) in patients (n = 862) who had DME with central involvement. A prespecified secondary endpoint of the studies assessed patients' DR severity score at year 2.

In VISTA, 38% of patients in the treatment groups achieved a two-step or better improvement on a DR severity scale, compared with 16% of patients in the control group; in VIVID, approximately 30% of patients in the treatment group achieved a two-step or better improvement on the DR severity scale, compared with 8% of patients in the control group.

In addition to DR in the presence of DME, aflibercept is FDA-approved for treatment of neovascular age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), and DME.

With the FDA approval, aflibercept becomes the second medication approved for DR in the presence of DME in less than a month. In late February, the FDA granted Genentech, maker of ranibizumab (Lucentis), approval to market the drug's 0.3-mg formulation for use in patients with DR in the presence of DME.

European Marketing Authorization Application Accepted for Uveitis Drug

The European Medicines Agency has accepted a marketing authorization application (MAA) filing for the use of intravitreal sirolimus (Santen Pharmaceutical), an investigational mTOR inhibitor, for the treatment of noninfectious uveitis in the posterior segment. Acceptance of the MAA filing marked the beginning of the regulatory review process, according to a press release.

The MAA filing included data from the SAKURA study, a phase 3 clinical trial. The MAA sought approval to market a 440-µg dose for chronic treatment of noninfectious uveitis in the posterior segment.

According to a press release, data from the SAKURA study supporting the approval of a 440-µg dose include data on the proportion of subjects achieving a vitreous haze score of 0 or 0.5+ at 5 months and the proportion of subjects successfully tapering off systemic corticosteroids at 5 months.

FDA Clearance Given to Navigated Laser System

The FDA has given marketing clearance to the Navilas 577+ (OD-OS) laser system, according to a press release. The Navilas 577+ features a navigated, yellow, 577-nm treatment laser and can perform tissue-friendly navigated microsecond-pulsed treatments.

The device is indicated for use in retinal photocoagulation in the treatment of clinically significant DME, proliferative DR, subretinal neovascularization, central and branch RVO, lattice degeneration, retinal tears, and retinal detachments.

IND Application Filed for Treatment of X-Linked Retinoschisis

Applied Genetic Technologies Corporation (AGTC) filed an investigational new drug (IND) application with the FDA to conduct a phase 1/2 clinical trial evaluating a gene

therapy product candidate for the treatment of X-linked retinoschisis (XLRS), according to a press release. The trial will evaluate the safety and efficacy of the product. The gene therapy in question uses an adeno-associated virus capsid with surface residues that are specifically engineered for penetration to the back of the eye.

If the FDA accepts the IND application, AGTC will initiate the study in the second quarter of 2015, and initial data are expected during the second half of 2015.

There are currently no FDA-approved treatments for XLRS.

Orphan Drug Designation Given to Gene Therapy for Choroideremia

The FDA and the European Medicines Agency have designated as an orphan drug NightstaRx's gene therapy for the treatment of choroideremia, according to a press release.

NightstaRx's gene therapy aims to treat choroideremia, an X-linked recessive disorder that leads to progressive blindness, by injecting a small modified virus, AAV2.REP1, to deliver the correct version of the choroideremia gene to cells in the retina.

The orphan drug designation means that the therapy's development and approval process will be expedited in both the United States and Europe.

Phase 2 IMPACT Study: Primary Endpoint Not Met, "Clinically Meaningful Benefit" in Classic CNV

The phase 2 IMPACT study failed to reach its primary endpoint, but the study demonstrated that OHR-102 (0.2% squalamine lactate ophthalmic solution, Ohr Pharmaceutical) combination therapy for the treatment of wet AMD had a "positive effect on visual acuity in classic [choroidal neovascularization]" early in the course of treatment and continuing through the end of the study, according to a press release.

Ohr said it plans to initiate a phase 3 study based on the outcomes of the IMPACT study.

The mean number of injections, which was the primary endpoint of the study, was similar in the combination OHR-102 and ranibizumab (Lucentis, Genentech) and ranibizumab monotherapy groups. Yet, patients with classic choroidal neovascularization (CNV) gained 10.5 letters on combination OHR-102 and ranibizumab compared with 5.4 letters among individuals assigned ranibizumab monotherapy, demonstrating a "clinically meaningful benefit of +5.1 letters," according to a press release announcing topline data from the study.

According to the press release, 42% of individuals in the intent-to-treat population with classic containing CNV gained three or more lines of visual acuity at 9 months compared with 28% in the monotherapy ranibizumab group. However, the press release said, "less of a benefit was seen in the overall population (classic containing and occult only CNV lesions)."

Additional data from the study will be presented at the upcoming Association for Research in Vision and Ophthalmology scientific meeting, the press release said.

Suprachoroidal Steroid Did Not Increase IOP in Uveitis Trial

Patients with noninfectious uveitis treated with a single suprachoroidal injection of a commercially available formulation of triamcinolone acetonide using a microinjector showed no meaningful increase in intraocular pressure in a phase 1/2 clinical trial, according to a press release.

Clearside Biomedical "believes that the suprachoroidal administration of steroid in the eye using [the] microinjector may avoid or reduce some of [the] side effects that are commonly seen when steroids are delivered via eye drops or intravitreal injection," according to a press release.

Participants (n = 8) in the trial showed improvement in BCVA from baseline at week 12 (2 lines) and week 26 (nearly 3 lines). Also, a reduction in retinal thickness was observed at weeks 12 and 26; the reductions were greater than 100 µm from their respective baselines.

No New Safety Events Seen in Ocriplasmin Study at 24 Months

No new safety signals were observed at 24 months following injection of ocriplasmin (Jetrea, ThromboGenics), according to a press release.

The OASIS study, a randomized, sham-controlled, double-masked study assessing the safety and efficacy of ocriplasmin in patients with vitreomacular adhesion, followed patients for 24 months after injection. No new safety events were reported, which is consistent with the drug's overall safety profile. The 24-month follow-up period is the longest period patients have been studied after ocriplasmin treatment. ■