

GENENTECH UPDATE: PFS APPROVAL, sBLA AND PRIORITY REVIEW FOR mCNV, AND BREAKTHROUGH DESIGNATION FOR GCA

The US Food and Drug Administration (FDA) approved the 0.5-mg prefilled syringe (PFS) of ranibizumab (Lucentis, Genentech) as a new method of delivering medicine. The regulatory body also granted Genentech a supplemental biologics license application (sBLA) and priority review for ranibizumab for the treatment of myopic choroidal neovascularization (mCNV) and granted breakthrough therapy designation status to tocilizumab (Actemra, Genentech) for giant cell arteritis (GCA).

PFS

FDA approval for the 0.5-mg PFS specifically states that the PFS may be used to treat patients with wet age-related macular degeneration (AMD) and macular edema secondary to retinal vein occlusion. The ranibizumab PFS is the first syringe prefilled with an anti-VEGF medicine FDA-approved to treat two eye diseases. The PFS is expected to be available by early 2017.

AAO Roundup

For a summary of the biggest news from the American Academy of Ophthalmology 2016 Annual Meeting visit bit.ly/aao2016. EyewireTV's live broadcast from the meeting exhibition floor will fill you in.



sBLA and Priority Review

In granting an sBLA to ranibizumab for the treatment of mCNV, the FDA relied on data from the phase 3 RADIANCE study. Data from that study demonstrated that treatment with ranibizumab provided superior visual acuity gains in patients with mCNV compared with verteporfin photodynamic therapy (PDT). After 3 months of treatment with 0.5 mg ranibizumab in RADIANCE, patients in a monthly injection group gained 10.6 letters and patients in a prn group gained 10.5 letters; patients who received verteporfin PDT gained 2.2 letters. Verteporfin PDT is the only treatment approved by the FDA for management of mCNV.

Priority review designation is granted to applications for medicines that treat serious conditions and, if approved, would provide a significant improvement in safety or efficacy.

Breakthrough Therapy

Breakthrough therapy designation is intended to expedite the development and review of therapies that may offer significant benefit to patients. No therapies have been approved for GCA in more than 50 years. GCA, caused by inflammation of large- and medium-sized arteries, can lead to blindness if untreated.

Regeneron, Ocular Therapeutix Deal Announced

Ocular Therapeutix announced that it has entered into a strategic collaboration, option and license agreement with Regeneron Pharmaceuticals to collaborate on the development of a sustained-release formulation of aflibercept (Eylea, Regeneron) for treatment of wet AMD, according to a company press release. The deal could be worth up to \$305 million in milestone payments.

Under the terms of the agreement, Ocular Therapeutix

and Regeneron will aim to develop a sustained-release formulation of aflibercept that is suitable for advancement into clinical development. Ocular Therapeutix is developing proprietary sustained-release, hydrogel-based drug delivery depots for intravitreal injection. The drug delivery depots can be formulated with both small and large molecule pharmaceuticals, such as tyrosine kinase inhibitors and protein-based anti-VEGFs, respectively, with the goal of delivering sustained and therapeutic levels of drugs to targeted ocular tissues.

Phase 2b DEL MAR Study Releases Topline Results

The phase 2b DEL MAR study, evaluating safety and efficacy of ALG-1001 (Luminate, Allegro Ophthalmics), met its primary and secondary endpoints, according to a company news release.

In DEL MAR, a controlled, double-masked, multicenter, dose-ranging study, 136 patients with diabetic macular edema were enrolled in one of three ALG-1001 arms (1 mg, 2 mg, and 3 mg) treated with three monthly injections of the drug followed by 12 weeks off treatment, or to a 1.25-mg bevacizumab (Avastin, Genentech) arm treated with six monthly injections.

The primary endpoint was noninferiority to bevacizumab, defined as difference of less than 3 letters in BCVA at 20 weeks. Patients in the 1.0-mg ALG-1001 arm gained 5.2 letters 12 weeks after the most recent injection, compared with 7.0 letters gained by patients in the arm that received monthly bevacizumab injection.

The secondary endpoint was noninferiority to bevacizumab, defined as ≤ 30 μm difference, in mean change in central macular thickness (CMT) as measured on optical coherence tomography (OCT). At week 20, patients in the 1.0-mg ALG-1001 arm showed mean reduction of 77 μm 12 weeks after the most recent injection, compared with 104 μm mean reduction in CMT in the monthly bevacizumab arm.

Safety results for the study were consistent with previous studies of ALG-1001. There were no reports of significant inflammation, no afferent pupillary defects, and no evidence of retinal tears or detachments.

Swept-Source OCT Device Cleared by FDA

The FDA approved the PLEX Elite 9000 (Carl Zeiss Meditec), the first swept-source OCT technology for imaging posterior ocular structures, according to a company press release.

The device is designed to be part of the core of the Advanced Retina Imaging network, a global consortium of

clinicians focused on exploring new clinical applications for the diagnosis and treatment of eye diseases.

The widefield high-resolution visualization provided by the device allows clinicians to examine microstructures and microvasculature of the posterior segment at any depth of interest, says the company.

New Photocoagulator Released

Lumenis announced the launch of the Smart 532 photocoagulator.

The device is powered by SmartPulse subthreshold technology and provides superior laser stability due to its advanced laser cavity technology, according to a company press release.

First Visual Cortical Prosthesis Implanted

The first successful implantation and activation of a wireless visual cortical stimulator (Orion I, Second Sight Medical Products) in a human subject has occurred, per a company press release.

The device was implanted in a 30-year-old patient who reported the ability to perceive and localize individual spots of light with no significant adverse side effects. The implant was performed as part of a proof-of-concept clinical trial with the purpose of demonstrating initial safety and feasibility of human visual cortex stimulation, states the press release.

Second Sight Medical Products is prepared to submit an application to the FDA in early 2017 to gain approval for conducting an initial clinical trial of the complete system, which will include a camera and glasses, the press release reports. ■

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