FIRST COMMERCIAL USE OF XEN IN UNITED STATES

Allergan's Xen Glaucoma Treatment System is now being used by US surgeons to treat refractory glaucoma, according to a company news release. The Xen Glaucoma Treatment System, consisting of the Xen45 Gel Stent and the Xen Injector, reduces IOP and is indicated for the management of refractory glaucoma where previous surgical treatment has failed and in patients with primary open-angle, pseudoexfoliative, and pigmentary glaucoma that is unresponsive to maximum tolerated medical therapy. The Xen45 is implanted through an ab interno approach and reduces IOP by creating a new drainage channel with a permanent implant that becomes flexible when hydrated. More than 12,000 Xen45 Gel Stents have already been distributed worldwide.

Bausch + Lomb, Nicox Resubmit NDA for Latanoprostene Bunod

Bausch + Lomb and Nicox resubmitted a new drug application to the FDA seeking approval for latanoprostene bunod ophthalmic solution, 0.024%. Latanoprostene bunod is an IOP-lowering single-agent eye drop dosed once daily for patients with open-angle glaucoma or ocular hypertension. The data submitted support latanoprostene bunod as the first nitric-oxide donating prostaglandin F2α analogue for ophthalmic use, the company reported. The FDA has set a Prescription Drug User Fee Act date of August 24, 2017.

Santen and TwoXar Form Strategic Research Collaboration

Santen and TwoXar, an artificial intelligence-driven biopharmaceutical company, have entered into a strategic research collaboration focused on the identification of new drug candidates for glaucoma. Under the agreement, TwoXar will use its proprietary computational drug discovery platform to discover, screen, and prioritize novel drug candidates with potential application in ocular indications, with a specific focus on glaucoma, according to a press release. Santen will have the exclusive right to develop and commercialize drug candidates arising from the collaboration.

Nicox resubmits AC-170 NDA

Nicox resubmitted the new drug application for AC-170, its novel, proprietary, cetirizine eye drop formulation for the treatment of ocular itching associated with allergic conjunctivitis. Nicox received confirmation that the FDA's Current Good Manufacturing Practice concerns surrounding the production site of the active pharmaceutical ingredient, cetirizine, have been resolved. Once the application is resubmitted, the FDA has 30 days to acknowledge its receipt, state the classification, and provide the due date for action, with a maximum review period of 6 months.

AMA Grants 5-Year Extensions for CPT Codes Related to MIGS

The Current Procedural Terminology (CPT) Editorial Panel of the American Medical Association has granted 5-year extensions to three Category III CPT codes that describe insertion of aqueous drainage devices into the anterior chamber of the eye using microinvasive glaucoma surgery, according to a Glaukos press release. In consultation with and with the support of the American Academy of Ophthalmology, American Glaucoma Society, and American Society of Cataract and Refractive Surgery, Glaukos requested and received extensions through December 31, 2023, on the following Category III CPT codes:

• 0191T, which describes insertion of an initial anterior segment aqueous drainage device such as Glaukos' iStent Trabecular

Micro-Bypass Stent and iStent Inject Trabecular Micro-Bypass Stent into the trabecular meshwork. The iStent was approved by the FDA and launched in 2012. The iStent Inject is currently being evaluated in US clinical trials and has not been approved by the FDA.

• 0253T, which describes insertion of an anterior segment aqueous drainage device such as Glaukos' iStent Supra Suprachoroidal Micro-Bypass Stent into the suprachoroidal space. The iStent Supra is currently being evaluated in US clinical trials and has not been approved by the FDA.

• 0376T, which is an add-on code that describes insertion of additional anterior segment aqueous drainage devices, as with the iStent Inject.

National Eye Health Education Program Offers Educational Resources

In celebration of Glaucoma Awareness Month, the National Eye Health Education Program (NEHEP) released educational resources in English and Spanish, which are available at bit.ly/NEHEP. NEHEP is a program of the National Eye Institute at the National Institutes of Health and emphasizes the importance of the early detection of glaucoma through comprehensive dilated eye exams. NEHEP recommends using the resources to educate patients about glaucoma and to promote the glaucoma benefit under Medicare. Visit bit.ly/NEHEP to access the resources.

Sanoculis Receives CE Mark for Minimally Invasive Microsclerotomy Device

The Sanoculis minimally invasive microsclerostomy (MIMS) device and procedure have been granted the CE Mark, enabling market launch in Europe. Sanoculis now plans to conduct a large-scale, multicenter clinical trial at several locations in Europe. The MIMS device has been shown to reduce IOP in glaucoma patients, either as a standalone procedure or in combination with cataract surgery, according to the company. The MIMS procedure is performed ab externo by creating a sclerocorneal channel to drain the aqueous humor from the anterior chamber to the subconjunctival space.

Nemus, Nanometrics Join to Treat Glaucoma With Molecular Envelope Technology

Nemus Bioscience signed a development agreement with Nanomerics to develop a topical ocular formulation of tetrahydrocannabinol-valine-hemisuccinate (THCVHS), the prodrug of THC. This is the active component of the Nemus drug candidate NB1111, which is being developed for the treatment of glaucoma, according to a news release. The aim of the agreement is to conduct initial studies assessing the preparation of clinical-grade eye drops using the patented molecular envelope technology (MET) developed by Nanomerics.

"Historically, it has been challenging to formulate hydrophobic, or fat-soluble, cannabinoid molecules for efficient and predictable entry into the body, especially the eye," Brian Murphy, MD, MBA, Nemus CEO and chief medical officer, said in a company news release. "Nemus has found the MET technology profile to be supportive of the work performed to date using the more hydrophilic THCVHS, which was designed to cross physiologic barriers more efficiently. Developing this formulation is an important step before conducting human studies."

"We feel that the MET platform will help NB1111 deliver in the clinic what has already been shown in several animal studies: namely, penetration into multiple chambers of the eye, a nonopaque eye drop, and a neutral pH at delivery to lower the risk of eye irritation, which is an adverse event seen with some established therapies in glaucoma," Nanomerics' CSO and cofounder professor Ijeoma Uchegbu said.

FDA Clears Icare Home for IOP Self-Monitoring

The FDA has cleared the Icare Home tonometer for use in the United States. The device provides data on how IOP fluctuates during the day, according to a press release. The device's lights help patients correctly position the tonometer, and an automated measuring sequence can take either a single or a series of six measurements. It involves no air puff or eye drops. ■