FDA Accepts NDA Submission for Rhopressa

Aerie Pharmaceuticals received notification that the FDA has completed its initial 60-day review of the Rhopressa (netarsudil ophthalmic solution) 0.02% new drug application and determined that the application is sufficiently complete to permit a substantive review, according to a press release.

The Prescription Drug User Fee Act goal date for the completion of the FDA’s review is set for February 28, 2018. This date reflects a standard 12-month review period and is consistent with Aerie’s expectations.

The notification also indicated that the FDA has not identified any potential review issues and that it is currently planning to hold an advisory committee.

Rhopressa is a novel eye drop that, if approved, would become the only once-daily product available that specifically targets the trabecular meshwork, according to Aerie.

Preclinical and clinical studies have also demonstrated that Rhopressa lowers episcleral venous pressure, and it may provide an additional mechanism that reduces fluid production in the eye and therefore lowers IOP.

Biochemically, the active ingredient in Rhopressa, netarsudil, has been shown in Aerie studies to inhibit both Rho kinase and norepinephrine transporter.

Recent preclinical studies have also shown that Rhopressa may have disease-modifying properties, including an anti-fibrotic effect of netarsudil on trabecular meshwork cells and the potential to increase perfusion of the trabecular meshwork.
Massachusetts Considers Allowing Optometrists to Treat Glaucoma

A provision in the Massachusetts’ state budget would permit optometrists to treat glaucoma and prescribe oral medications for eye infections, according to US News & World Report. Massachusetts is the only state that mandates that glaucoma patients must visit an ophthalmologist for these services. At press time, the budget had not yet been passed.

Glaukos Acquires IOP Sensor System From Dose Medical

Glaukos acquired the IOP sensor system assets and related liabilities from Dose Medical for $5.5 million in cash, plus performance-based consideration of up to $9.5 million upon achievement of certain development, clinical, and regulatory milestones, according to a press release.

The Dose Medical IOP sensor system features a microinvasive ocular implant that is designed to capture and store a glaucoma patient’s short-interval IOP measurements over extended periods of time and transmit data to the patient’s physician in order to enhance treatment decisions. The wireless system, which is designed for ab interno insertion, incorporates a rechargeable battery that may allow the sensor to function for multiple years.

“Although still in an early development phase, the system offers future promise as a 24/7 tool for measuring the effects of glaucoma medical and surgical interventions, monitoring patient therapeutic compliance, and managing disease progression,” Thomas Burns, Glaukos’ president and chief executive officer, said in a company news release.

Dose Medical was previously a wholly owned subsidiary of Glaukos. In 2010, it was spun out as a standalone entity separate from Glaukos’ go-forward business. In 2015, Glaukos acquired the iDose product line and related assets from Dose Medical. Two Glaukos directors also serve on the board of Dose Medical. The terms of the transaction were approved by a special committee consisting only of independent members of Glaukos’ board of directors.

In Remembrance: Prof. Peter Watson

Prof. Peter Watson, a clinician-scientist who was recognized internationally for his world-leading research, passed away in February. He and John Cairns, MD, revolutionized the practice of ophthalmology with their invention of trabeculectomy for the surgical treatment of glaucoma. Prof. Watson’s textbook on scleritis redefined the field and became the standard reference.

In remembrances, he was described as an excellent teacher, a great friend, a mentor, and one of the giants on whose shoulders ophthalmologists are standing.

Health Canada Approves Visco360 for Standalone MIGS

Health Canada approved the Visco360 Viscosurgical System (Sight Sciences) for the microcatheterization and transluminal visقودilation of Schlemm canal to reduce IOP in adult patients with open-angle glaucoma, according to a press release.

The Visco360 System is a fully integrated, single-handed, single-use device that offers a single-incision, 360° canal procedure. The system combines a custom-access cannula; a soft and flexible microcatheter with an atraumatic tip; an internal infusion pump, gear mechanism, and viscoelastic reservoir; and a wheel that controls advancement and retraction of the microcatheter using a single finger.

Imprimis Launches Simple Drops Combination Glaucoma Drops

Imprimis Pharmaceuticals announced the launch of its new patent-pending Simple Drops preservative-free glaucoma drops. Simple Drops preservative-free drops conveniently provide multiple glaucoma medications in a single bottle.

Clearing the Record

In its March/April 2017 edition, GT misidentified the manufacturer of the Xen Glaucoma Treatment System. The manufacturer is Allergan.
2017
June 20 to July 1
Helsinki, Finland
7th World Glaucoma Congress
www.worldglaucomacongress.org

September 25 to 26
London
19th International Conference on Glaucoma Surgery
bit.ly/glaucomasurgery

November 11 to 14
New Orleans
American Academy of Ophthalmology Annual Meeting
www.aao.org/annual-meeting

2018
February 8 to 10
San Francisco
Glaucoma 360
www.glaucoma.org

March 1 to 4
New York
American Glaucoma Society Annual Meeting
www.americanglaucomasociety.net

May 3 to 7
San Diego
American Society of Cataract and Refractive Surgery Congress & Symposium
www.ascrs.org