# HYDRUS MICROSTENT MEETS ENDPOINTS

The HORIZON pivotal study of the Hydrus Microstent has met the 2-year primary and secondary endpoints, Ivantis reported in a press release. The HORIZON study included 556 patients and was designed to demonstrate the safety and efficacy of the Hydrus Microstent in lowering IOP in glaucoma patients undergoing cataract surgery.

The two-year follow-up data from the trial showed that 77.2% of patients achieved a 20% or greater reduction in IOP, compared to 57.8% of patients in the cataract-only group. The device reduced IOP 43% more than cataract surgery alone (7.6 vs 5.3 mm Hg). Furthermore, 78% of Hydrus patients remained medication free compared with 48% in the control group.

The treatment effect in the Hydrus group increased from year 1 to year 2 as compared to the control group, suggesting an increasing benefit over time.

Roughly the size of an eyelash, the Hydrus Microstent is designed to reduce eye pressure by reestablishing flow through Schlemm canal. It creates a bypass through the trabecular meshwork, allowing outflow of aqueous humor, then dilates and scaffolds Schlemm canal to augment outflow. It spans 90°of the canal to provide consistent access to the fluid collector channels in the eye.

Ivantis is preparing for the commercial release of the Hydrus in 2018.

## Next-Generation Eyemate Passes First-in-Human Validation

Implandata Ophthalmic Products' next-generation Eyemate microsensor implant successfully passed first-in-human validation, the company reports. The Eyemate system uses a microsensor (to be implanted in conjunction with cataract, glaucoma or corneal surgery, ultimately also in a stand-alone procedure) to directly measure IOP. The sensor that is currently available (not FDA approved) requires a 4-mm incision, but this next-generation sensor will reduce the incision size to 2.7 mm or less.

## FDA Approves Vyzulta

In November, the FDA approved the new drug application for Vyzulta (latanoprostene bunod ophthalmic solution) 0.024% (Nicox and Bausch + Lomb), a prostaglandin indicated for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension. Following topical administration, Vyzulta, a once-daily monotherapy with a dual mechanism of action, works by metabolizing into two moieties, latanoprost acid, which primarily works within the uveoscleral pathway to increase aqueous humor outflow, and butanediol mononitrate, which releases nitric oxide to increase outflow through the trabecular meshwork and Schlemm canal.

## Report: Combination Therapies to Boost the Glaucoma Therapeutics Market

According to the latest report by Technavio market research analysts, the global glaucoma therapeutics market is expected to grow at a compound annual growth rate of close to 4% from 2017 through 2021. Three market drivers are contributing to the growth: an increasing geriatric population, the advent of new, innovative combination drugs, and an unmet need in the glaucoma therapeutics market.

**77%**

**percentage of patients who achieved at least a 20% reduction in IOP with the Hydrus Microstent**

**2.7 mm**

**Incision size needed for the next-generation Eyemate microsensor implant**

**4%**

**Projected compound annual growth rate in the glaucoma therapeutics market through 2021**

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Travelling at 50 MPH, a champagne cork can cause serious eye injury and blindness. Revelers can take steps to protect themselves.
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2. **Eye Drops Are Intentionally Wasteful**
Why do drug companies make eye drops larger than the eye can hold? Because they are much more profitable that way.
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3. **Man Recovers From Spinal Cord Injury**
Six years after a complete spinal cord injury, a man has regained the ability to move his legs and stand.
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4. **Heart Attack Gender Gap**
Women are more likely than men to die in the first year after a heart attack. Scientists urge doctors to take note.
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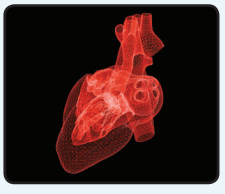

5. **Simulator Training Makes New Surgeons Faster**
Brain imaging shows that simulator-trained medical students successfully transfer skills to operating on cadavers and are faster at cutting tasks than their peers who had no simulator training.
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## Mitosol's Orphan Drug Designation Expanded

Mobius Therapeutics expanded its orphan drug designation for Mitosol to now read, "treatment of refractory glaucoma as an adjunct to surgery." By expanding this orphan drug indication, Mobius may now assume the benefits of orphan drug designation for new and evolving microinvasive glaucoma surgery procedures.

## iStar Medical Completes Enrollment of First-in-Human MIGS Trial

The first-in-human microinvasive glaucoma surgery trial for the Miniject device (iStar Medical) has completed enrollment, according to a press release. The prospective, open, international, multicenter study has recruited 25 patients with mild to moderate open-angle glaucoma uncontrolled by topical hypotensive medications. The aim of the study is to assess the safety and performance of the Miniject device as measured by IOP reduction from baseline to 6 months. Subsequent safety and performance will be measured at 12 and 24 months after surgery. Miniject enhances aqueous humour outflow from the anterior chamber to the suprachoroidal space.

## FDA Advisory Committee Votes in Favor of Rhopressa

In their review of Aerie Pharmaceuticals' product candidate Rhopressa (netarsudil ophthalmic solution) 0.02%, the members of the FDA's Dermatologic and Ophthalmic Drugs Advisory Committee provided a favorable vote. In addition, there was general discussion on suggestions regarding the draft product labeling proposed by the FDA, which will ultimately be determined based on follow-on discussions between Aerie and the FDA. The goal date for the FDA to take action under the Prescription Drug User Fee Act is February 28, 2018.

## Clearing the Record

In the September/October 2017 edition, the article "Compounded Glaucoma Medications" by Lauren Seo and Nathan Radcliffe, MD, misidentified the manufacturer of the compounded formulation. The corrected statements are as follows: "Although the four-drop therapy from Ocular Science contains benzalkonium chloride (BAK) as a preservative, the concentration is 0.001%—much lower than in typical generic preparations. In total, Ocular Science's compounded formulation would expose a patient to 0.002% BAK (0.001% × 2 doses = 0.002%), whereas using the same agents in separate bottles would amount to an exposure of 0.06%, a 30-fold increase ([latanoprost with 0.02% BAK × 1 dose] + [timolol with 0.01% BAK × 2 doses] + [dorzolamide with 0.0075% BAK × 2 doses] + brimonidine with 0.005% BAK = 0.06%)." ■