Ivantis Announces FDA Approval for Its Innovative Hydrus® Microstent Device for Minimally Invasive Glaucoma Surgery (MIGS)

The Next-Generation MIGS Device, Implanted During Cataract Surgery, Lowers Intraocular Pressure in Patients with Glaucoma, a Leading Cause of Blindness

NEWS PROVIDED BY
Ivantis, Inc. →
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IRVINE, Calif., Aug. 13, 2018 /PRNewswire/ -- Ivantis, a company dedicated to developing new and innovative solutions for glaucoma, announced today that it received Food and Drug Administration (FDA) approval for the Hydrus® Microstent, a microinvasive glaucoma surgery (MIGS) device used to treat patients with mild to moderate primary open-angle glaucoma in conjunction with cataract surgery.

The FDA approval is based on the landmark HORIZON Trial, the largest MIGS study ever conducted. The study included 556 mild to moderate glaucoma patients undergoing cataract surgery, randomized to either receive cataract surgery plus the Hydrus Microstent (treatment) or cataract surgery alone (control). More than three-quarters (77.2 percent) of patients in the Hydrus Microstent group achieved a statistically significant decrease (≥ 20 percent reduction in unmedicated intraocular pressure) at 24-months postoperative, compared to 57.8 percent in the cataract surgery alone group, meeting the primary effectiveness endpoint. This represents the largest improvement over control reported in any MIGS pivotal trial to date.

The secondary effectiveness endpoint was also met, with Hydrus Microstent patients achieving a mean intraocular pressure (IOP) reduction of 7.5 mmHg, a difference of 2.3 mmHg compared to cataract surgery alone. Several epidemiological studies have shown that each point of IOP reduction reduces the risk of progression of glaucoma. The 43 percent improvement for the treatment group over control is also the largest of any MIGS pivotal trial to date. The HORIZON Trial results have been accepted for publication in Ophthalmology, the leading journal in the field (in press, available online June 23, 2018).

According to David F. Chang, M.D., clinical professor of Ophthalmology at the University of California, San Francisco, "Ophthalmologists in the U.S. will certainly welcome the approval of a next-generation canal-based MIGS device. The Hydrus Microstent scaffolds approximately 90 degrees of the patient's natural canal outflow pathway. Correct anatomic placement into the canal will also be easier for surgeons to confirm. The overall body of clinical data supporting Hydrus is very encouraging in terms of both safety and two-year efficacy and sets a new bar for the treatment of mild to moderate glaucoma in cataract patients. It also appears to be very effective at eliminating medications, compared to cataract surgery alone. I look forward to offering Hydrus to my patients."

"We are pleased by the FDA's approval of our Hydrus Microstent," said Dave Van Meter, President and CEO of Ivantis. "Although the device has been used in over 4,000 procedures internationally, many of which are now well past five years, the Hydrus Microstent represents a novel device platform to FDA, and this approval occurred within our projected timeline. We are now proceeding with building our commercial and manufacturing infrastructures and intend to launch the product later this year. We thank the FDA for their timely review, and we look forward to Hydrus Microstent becoming an important part of the cataract surgeons' and glaucoma specialists' surgical armamentarium."

About the Hydrus Microstent

Roughly the size of an eyelash, the Hydrus Microstent is a next-generation MIGS device designed to reduce eye pressure by reestablishing flow through Schlemm's canal, the eye's natural outflow pathway. When placed into the trabecular meshwork and the canal during microinvasive glaucoma surgery, the aqueous drainage device restores the flow of fluid in the eye using a trimodal mechanism of action:

1. The Hydrus Microstent creates a bypass through the trabecular meshwork, allowing outflow of aqueous humor.
2. It then dilates and scaffolds Schlemm's canal to augment outflow.
3. Its length spans 90 degrees of the canal to provide consistent access to the fluid collector channels in the eye.

The Hydrus Microstent is one of the most rigorously researched and thoroughly studied of all MIGS devices, with more than 4,000 cases treated globally, in patients with a wide range of disease severities.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE:

The Hydrus Microstent is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG).

CONTRAINDICATIONS:

The Hydrus Microstent is contraindicated under the following circumstances or conditions: (1) In eyes with angle closure glaucoma; and (2) In eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber (AC) angle.

WARNINGS

Clear media for adequate visualization is required. Conditions such as corneal haze, corneal opacity or other conditions may inhibit gonioscopic view of the intended implant location. Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, peripheral anterior synechiae (PAS), angle closure, rubeosis and any other angle abnormalities that could lead to improper placement of the stent and pose a hazard.

PRECAUTIONS

The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The safety and effectiveness of the Hydrus Microstent has not been established as an alternative to the primary treatment of glaucoma with medications, in patients 21 years or younger, eyes with significant prior trauma, eyes with abnormal anterior segment, eyes with chronic inflammation, eyes with glaucoma associated with vascular disorders, eyes with preexisting pseudophakia, eyes with uveitic glaucoma, eyes with pseudoexfoliative or pigmentary glaucoma, eyes with other secondary open angle glaucomas, eyes that have undergone prior incisional glaucoma surgery or cilioablative procedures, eyes that have undergone argon laser trabeculoplasty (ALT), eyes with unmedicated IOP < 22 mmHg or > 34 mmHg, eyes with medicated IOP > 31 mmHg, eyes requiring > 4 ocular hypotensive medications prior to surgery, in the setting of complicated cataract surgery with iatrogenic injury to the anterior or posterior segment and when implantation is without concomitant cataract surgery with IOL implantation. The safety and effectiveness of the use of more than a single Hydrus Microstent has not been established.

ADVERSE EVENTS

Common postoperative adverse events reported in the randomized pivotal trial included partial or complete device obstruction (7.3 percent); worsening in visual field MD by > 2.5 dB compared with preoperative (4.3 percent vs. 5.3 percent for cataract surgery alone); device malposition (1.4 percent); and BCVA loss of ≥ 2 ETDRS lines ≥ three months (1.4 percent vs. 1.6 percent for cataract surgery alone). For additional adverse event information, please refer to the Instructions for Use.

MRI INFORMATION

The Hydrus Microstent is MR-Conditional meaning that the device is safe for use in a specified MR environment under specified condition, please see the Instructions for Use and Patient Information Card for details.

Please refer to the Instructions for Use for complete product information.

About Ivantis

Ivantis, Inc. is a privately held company established in 2007 to design, develop and commercialize new technologies to treat eye disease. Investors include New Enterprise Associates, Delphi Ventures, Foresite Capital, RA Capital Management, Ascension Ventures, EDBI, GBS Ventures, MemorialCare Innovation Fund, Merieux Development and Vertex HealthCare. The company is headquartered in Irvine, California.

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