Ivantis Announces Results of Landmark Prospective, Randomized Comparative MIGS Clinical Trial

International Multi-center Study Compares Effectiveness of the Hydrus® Microstent to Two Glaukos iStent® Trabecular Micro-Bypass Stents in Standalone Glaucoma

Washington, D.C. / IRVINE, Calif., April 16, 2018 – Ivantis Inc., developer of the novel Hydrus® Microstent, a device designed to lower eye pressure for open-angle glaucoma patients, announced today the 12-month results of the COMPARE study for minimally invasive glaucoma surgery (MIGS). Results from the study will be presented by David Chang, MD, clinical professor of Ophthalmology at the University of California, San Francisco, during the American Society of Cataract and Refractive Surgery (ASCRS) meeting in Washington, D.C. at 2:02pm EDT today in the Walter E. Washington Convention Center – MIGS Level 1, room 149AB.

COMPARE is the first prospective, multi-center, randomized trial comparing two MIGS devices, the Hydrus Microstent versus two large-diameter iStent® Trabecular Micro-Bypass Stents (Glaukos Corp.), for the treatment of open-angle glaucoma in a standalone procedure. The trial included 152 patients with mild to late-moderate stage disease and was conducted at 12 centers in eight countries outside of the US. It was designed to compare the safety and effectiveness of both devices in lowering intraocular pressure (IOP) and reducing eye-drop medication. The comparative trial involved experienced MIGS surgeons who were beyond their surgical learning curves for both devices. The trial was designed to be a pure head-to-head comparison of devices without the confounding effect of cataract surgery, which has also been shown to lower IOP.

Iqbal "Ike" Ahmed, MD, distinguished Binkhorst medal recipient and lecturer at ASCRS on the topic of MIGS, and a Scientific Advisory Board member for both technologies studied in COMPARE, served as medical monitor for the trial. Dr. Ahmed stated, "This is a necessary, novel and well-run study conducted by a group of experts in the field of MIGS. Not only is it the first to compare two different canal-based technologies in a Level One evidence clinical trial, but it is the first prospective, randomized data reported where we can evaluate MIGS devices in a standalone glaucoma setting. These MIGS approaches, when combined with cataract surgery, have been previously reported to be safe and effective. This study looks at the viability of MIGS in patients who don't need or may have already had cataract surgery, so it's a vital addition to our growing body of evidence supporting MIGS."

The 12-month results showed the following:

- 47 percent of eyes in the Hydrus Microstent group were medication free, compared to 24 percent of eyes in the two-iStent group.
- Medication use was reduced on average by 1.6 medications, or 61 percent, in the Hydrus Microstent group, compared to a reduction of one medication, or 37 percent, in the two-iStent group.

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- 73 percent of patients receiving the Hydrus Microstent achieved at least a 20 percent reduction in IOP while on fewer medications, compared to 47 percent of the two iStent patients.

Dr. Thomas W. Samuelson, global medical monitor for Ivantis, added: "To date, we have had no comparative data from prospective randomized studies evaluating two different MIGS devices. Furthermore, we have had very few, if any, Level One evidence clinical trials assessing MIGS in a standalone glaucoma surgery setting. COMPARE is not only a multi-center study but also a 'real world' MIGS assessment, given the wide range of glaucoma severity and the fact that 12 experienced, expert surgeons from eight countries participated. It is notable that participation criteria required that all surgeons were past the learning curve for each MIGS platform. The COMPARE data will be helpful in evaluating canal-based MIGS in a wide range of clinic situations, and demonstrates the benefit of dilating Schlemm's canal and gaining access to multiple outflow collector channels. I look forward to the peer-reviewed publication of these results and further analysis with longer follow-up."

"These results illustrate the clinical advantages of the Hydrus and its unique, proprietary Tri-Modal mechanism of action," said Dave Van Meter, President and CEO of Ivantis. "Combined with best-in-class data in the cataract surgery setting, this adds to what we believe is the broadest and highest-level evidence seen to date for a MIGS device. We are proud to sponsor clinical trials of this caliber, enabling the COMPARE investigators to advance our understanding of the Hydrus Microstent and the MIGS field overall, and we look forward to the publication of these important results. We are grateful to the investigators for their support and contributions."

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 in the canal during minimally invasive microsurgery, the device restores the flow of fluid in the eye, using a tri-modal 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 MIGS devices, with more than 3,500 cases treated globally, in patients with a wide range of disease severities.

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, Calif.

Hydrus Microstent is not currently approved for sale in the United States.

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