New Data from the HORIZON Trial of the Hydrus® Microstent Shows Significantly Lower IOP and Medication Use at 24 Months in a US Patient Cohort

Data are Best Results Reported To Date from a Randomized Controlled MIGS Study

IRVINE, Calif., April 12, 2018 – Ivantis Inc., developer of the novel Hydrus® Microstent device designed to lower eye pressure for glaucoma patients, announced today that the HORIZON US cohort data will be presented at the annual meeting of the American Society of Cataract and Refractive Surgery (ASCRS) in Washington, D.C., on Saturday, April 14, 2018. The full global HORIZON pivotal trial results were previously presented at the American Academy of Ophthalmology meeting last November.

The results will be presented by Dr. Iqbal "Ike" Ahmed, assistant professor at the University of Toronto, who serves as the Research Director at the Kensington Eye Institute and the Director of the Glaucoma and Advanced Anterior Segment Surgery (GAASS) Fellowship Program at the University of Toronto.

The US cohort analysis included 331 of the 556 HORIZON subjects (60 percent of all HORIZON eyes) treated in the United States at the 26 US centers that participated in the trial. The HORIZON Trial compared reductions in intraocular pressure (IOP) and ocular hypotensive medication use in patients having cataract surgery, with and without the Hydrus Microstent. Patients in the study had mild-to-moderate primary open angle glaucoma (POAG) and were taking one to four eye drops.

The 24 month US cohort data, analyzed with the conservative intention-to-treat methodology, showed:

- 79 percent of Hydrus Microstent patients achieved a 20 percent or greater reduction in IOP, compared to 55 percent in the cataract only group for a difference of 24 percent.
- Hydrus Microstent reduced IOP 50 percent more than cataract surgery alone (7.9 mmHg vs. 5.2 mmHg, a difference of 2.7 mmHg).
- Twice the number of Hydrus Microstent patients remained medication free compared to the control group (79 percent vs. 39 percent).
- Of patients on one eye drop at entry into the study, which represents the most common glaucoma patient in the US, 87 percent were medication free compared to 38 percent in the control group.

The treatment effect at 24 months for each of these metrics is the largest improvement over control of any MIGS pivotal trial reported to date.

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"These are the best results we have seen to date in a US patient population from a randomized controlled MIGS trial," said Dr. Ahmed. "As a glaucoma specialist, it's encouraging to see more robust improvements in IOP lowering compared to cataract surgery alone. A near 3-point improvement in IOP lowering compared to control is significant, and clearly this benefit will help keep patients on fewer medications. Whereas the global HORIZON results were excellent, the US cohort results appear even stronger and may give us even greater insights into differences in how patients are treated with MIGS from region to region. I look forward to a more detailed analysis of patient demographics and potential differences in practice patterns in the forthcoming publication."

Dr. Douglas Koch, Professor and Allen, Mosbacher, and Law Chair in Ophthalmology at Baylor College of Medicine, added, "The ability of the Hydrus device to keep patients medication free, and do so consistently for up to two years, with virtually the same safety profile as cataract surgery, is of utmost importance and should resonate with any busy cataract practice in the US. The surgery is elegant, straight forward, and easy to learn. When you consider this and the efficacy reported, I am certain that the Hydrus will become a widely adopted new MIGS solution. I am eager to have the opportunity to offer this to my patients when it becomes available."

The global HORIZON study is the largest prospective, randomized, controlled trial conducted to date for a MIGS device. The initial study included 556 patients and was conducted at 38 centers in nine countries on three continents and was designed to demonstrate the safety and efficacy of the Hydrus Microstent in lowering intraocular pressure in glaucoma patients undergoing cataract surgery.

"This data gives us great confidence that the Hydrus Microstent could become standard of care for glaucoma patients undergoing cataract surgery," said Dave Van Meter, President and CEO of Ivantis. "While we are proud to have conducted the first global MIGS pivotal trial in HORIZON, we also recognize that this analysis was an important step in allowing surgeons an opportunity to assess a US cohort of the HORIZON Trial and evaluate the Hydrus technology in the context of a growing body of MIGS clinical data."

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. Ivantis anticipates marketing approval of the Hydrus Microstent in the US in 2018.

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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