Ivantis FDA Clinical Trial of the Hydrus® Microstent for Minimally Invasive Glaucoma Surgery (MIGS) Meets Endpoints, Exceeds Outcomes of Past MIGS Trials

IRVINE, Calif., Nov. 13, 2017 – Ivantis Inc., developer of the novel Hydrus® Microstent, a micro-invasive glaucoma surgical (MIGS) device designed to lower eye pressure for open-angle glaucoma patients, announced today that the HORIZON pivotal study has met both the two year primary and secondary pre-established endpoints. Outcomes exceed those of any MIGS pivotal trial to date. Ivantis previously announced that it submitted the final module of the PMA containing the HORIZON trial results to the US Food and Drug Administration (FDA) for market approval.

The HORIZON study is the largest prospective, randomized, controlled trial conducted to date for a MIGS device, and the first to have a global span. The 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 (IOP) in glaucoma patients undergoing cataract surgery.

According to a presentation by Paul Harasymowycz, MD, given during the American Academy of Ophthalmology annual meeting in New Orleans, LA, the two-year follow-up data from the HORIZON trial showed that:

- 77.2 percent of Hydrus Microstent patients achieved a 20 percent or greater reduction in IOP, compared to 57.8 percent in the cataract-only group, the largest treatment effect reported in a MIGS pivotal trial at 24 months.
- Hydrus Microstent reduced IOP 43 percent more than cataract surgery alone (7.6 mmHg vs. 5.3 mmHg), the largest difference in IOP reduction reported in a MIGS pivotal trial at 24 months.
- 78 percent of Hydrus Microstent patients remained medication-free compared to 48 percent in the control group, again the highest margin of total medication elimination compared to control of any MIGS pivotal trial at 24 months.
- The treatment effect in the Hydrus Microstent group increased from year one to year two as compared to the control group, suggesting an increasing benefit over time.

“This was a very well-run trial, producing excellent, convincing, and compelling results,” said Thomas W. Samuelson, MD, Global Medical Advisor for Ivantis, and Vice President/President-elect of the American Society of Cataract and Refractive Surgeons. “Once again, as with the other MIGS trials previously published, the control group demonstrates that cataract surgery alone is an effective IOP lowering

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procedure, but that IOP lowering can be effectively enhanced in a safe, clinically meaningful, and enduring fashion with the Hydrus Microstent. Among the impressive results seen in HORIZON, what stands out to me is the increasing benefit over time with Hydrus Microstent versus cataract surgery alone. These results strengthen the case for the use of MIGS as the preferred approach for most patients with mild to moderate glaucoma undergoing cataract surgery."

"It's gratifying to see these results from the HORIZON Trial," said Jason Jones, MD, (Sioux City, IA) a principal investigator in the HORIZON trial and one of the highest volume cataract surgeons in the country. "I am a very busy anterior segment surgeon, and I require a MIGS solution that is efficient to implant, adds little risk, and offers glaucoma patients the best chance to be eyedrop-free when they leave our office. The Hydrus Microstent offers all of these and seems to do so with consistency. I am confident in the procedure and pleased to see that the broader HORIZON results mirror the experience in our clinic."

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 is preparing for the commercial release of the Hydrus Microstent, anticipating market approval in 2018.

"We are grateful to all of the HORIZON Study Investigators and research teams across the globe for their outstanding contributions in advancing not only the Hydrus Microstent clinical program but the MIGS category overall," said Dave Van Meter, President and CEO of Ivantis. "With these results, we've been able to demonstrate best-in-class clinical evidence in another top-level randomized controlled trial utilizing the ANSI Standard for implantable glaucoma devices, the highest level of evidence defined by the Food and Drug Administration. These excellent results give us great confidence that the Hydrus Microstent can become the standard of care for both cataract and glaucoma surgeons for the majority of their glaucoma patients undergoing cataract surgery."

About Glaucoma and MIGS

In the US, approximately 20 percent of the 3.7 million patients undergoing cataract surgery have a concurrent diagnosis of glaucoma[i]. The World Health Organization estimates that by 2020, 32 million cataract surgeries[ii] will be performed globally. In the US alone, approximately 740,000[iii] patients each year may be candidates for MIGS treatment.

The goal of any glaucoma surgery is to lower the pressure in the eye to limit damage to the optic nerve. Traditional eye surgeries, like a trabeculectomy or installing external shunts, are all major surgeries, with attendant risks. MIGS procedures use microscopic devices and tiny incisions to reduce the risk of complications.

About Ivantis

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

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[i] Ianchulev et al., Ophthalmology, Office-Based Cataract Surgery: Population Health Outcomes Study of More than 21 000 Cases in the United States, 2016 Apr;123(4):723-8. doi: 10.1016/j.ophtha.2015.12.020.
[ii] World Health Organization, Blindness: Vision 2020 fact sheet.
[iii] Tseng et al., Journal of the American Medical Association (JAMA), Risk of Fractures Following Cataract Surgery in Medicare Beneficiaries, 2012;308(5):493-501. doi:10.1001/jama.2012.9014.