Ivantis Announces FDA Clearance to Initiate Clinical Trial of the Hydrus™ Microstent for Minimally Invasive Glaucoma Surgery (MIGS) in Patients with Advanced Glaucoma

IRVINE, Calif., April 25, 2017 – Ivantis Inc., developer of the novel Hydrus™ Microstent device, designed to lower eye pressure for glaucoma patients, announced today that the US Food and Drug Administration (FDA) has granted the company clearance to initiate a second investigational device exemption (IDE) clinical trial of the Hydrus Microstent. This trial will involve patients with advanced glaucoma, undergoing stand-alone glaucoma surgery without combined cataract surgery.

The clearance comes on the heels of a $25 million Series C financing announced last quarter by Ivantis, in support of the anticipated 2018 FDA approval of the Hydrus Microstent in patients with mild to moderate glaucoma and undergoing cataract surgery.

The recently approved "SUMMIT" Trial will allow Ivantis to study the Hydrus Microstent in more challenging glaucoma cases, complementing the mild-to-moderate cataract-glaucoma patients who have already been studied for years. Ivantis is conducting this study to show that the Hydrus Microstent can combine the efficacy required for a later-stage approach with the safety surgeons demand for the treatment of early-stage patients.

"Thanks to the advent of minimally invasive glaucoma surgery (MIGS), we now have several tools in our armamentarium to treat this disease effectively. However, as we move into the more advanced glaucoma cases, we often need to sacrifice safety to achieve the necessary efficacy required to lower intraocular pressure," said Thomas Samuelson, MD, Medical Monitor for the SUMMIT trial. "The fact that Hydrus has the potential to be used on both ends of the glaucoma spectrum is an important differentiator since, from a labeling standpoint, no MIGS device has yet demonstrated the safety and efficacy to be considered for such broad use."

Roughly the size of an eyelash, the Hydrus Microstent is a next-generation MIGS device designed to reduce eye pressure by reestablishing the patient's natural outflow pathway, known as Schlemm's canal, through which fluid exits the eye. Most often, glaucoma patients have both a blockage and a collapse of the canal. The Hydrus Microstent, placed in the eye using a minimally invasive, microsurgical procedure, provides a tri-modal mechanism of action. The device opens a bypass through the traditional source of flow blockage, known as the trabecular meshwork. The Hydrus then dilates and scaffolds Schlemm's canal to augment outflow, and spans 90 degrees of the canal to provide expanded access to the eye's fluid collector channels.

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"With the addition of this second trial, the Hydrus Microstent will have been evaluated in a full range of mild to advanced glaucoma, representative of the approximately 5 million US patients with glaucoma," said Dave Van Meter, President and CEO of Ivantis. "We have followed thousands of patients through trials and registries, and our belief is that no other MIGS device provides the versatility, utility and combined safety and efficacy profile as the Hydrus Microstent in treating such a wide array of glaucoma, offering hope to both the patients debilitated by this blinding disease and the practitioners who care for them."

The newly approved trial will assess the 12-month safety and effectiveness of the device in 60 advanced glaucoma patients for whom conventional therapies to control intraocular pressure have proven unsuccessful. The study will add to the vast body of existing research on the Hydrus Microstent, already one of the most-studied glaucoma devices to date with more than 3,000 cases treated globally, in patients with a wide range of disease severities.

Prior trials on the Hydrus Microstent include:

- **HYDRUS II Study** – randomized controlled trial in Europe evaluating the Hydrus in glaucoma patients undergoing cataract surgery

- **HORIZON Study** – IDE randomized controlled trial in glaucoma patients undergoing cataract surgery, which the company expects to utilize to obtain a US approval in 2018

According to Dr. Leon Au, Consultant Ophthalmic Surgeon of Manchester Royal Eye Hospital in the United Kingdom, "As clinicians, we are constantly seeking to delay the traditional, most invasive glaucoma procedures in challenging patients, as late-stage glaucoma procedures tend to have a complication profile that is often undesirable. I've been able to evaluate the Hydrus over the past four years in an open-label registry, and am impressed with the device's versatility. The device offers me an option for my more advanced glaucoma patients that I have found to be both safe and effective. Most importantly, my patients who have received the Hydrus have been highly satisfied with their outcomes."

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.

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