For Immediate Release
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Ivantis Completes Enrollment in Pivotal HYDRUS IV Glaucoma Study of the Hydrus™ Microstent

Clinical Milestone is Major Step Forward to FDA Review of Innovative and Less Invasive Glaucoma Technology

IRVINE, Calif., -- Ivantis, Inc., developer of the novel Hydrus™ Microstent, today announced the completion of subject enrollment in its landmark HYDRUS IV pivotal trial. The study is being conducted at 36 centers worldwide and includes over 550 subjects. It is the largest randomized controlled MIGS (minimally invasive glaucoma surgery) study ever conducted.

An Investigator team at Keystone Research in Austin, Texas led subject enrollment in the United States. Dr. Robert Marquis commented, "As a busy glaucoma surgeon with experience in both traditional and the newer surgical approaches, I've been very impressed with Hydrus. I joined this study because of the science and engineering behind the device and its injector. The procedure is elegant and the implantation of the microstent has been safe and rewarding for my patients."

Dr. Richard Lewis, a glaucoma and cataract specialist in private practice in Sacramento, Calif., as well as a Scientific Advisor and Principal Investigator for Ivantis, commented, "This is a major accomplishment for Ivantis and represents significant progress for the Hydrus technology. Ivantis should be commended for their rigorous approach to evidence-based clinical evaluations of their product both here in the U.S. and abroad. It is important that we continue to look for new approaches to this challenging disease and I am looking forward to being able to offer the Hydrus upon its regulatory approval to my glaucoma patients."

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"We are proud to have completed this phase of the HYDRUS IV study," said Dave Van Meter, President and CEO of Ivantis. "We wish to acknowledge and congratulate the clinical investigators and study teams who made this milestone a reality. We now look forward to the important next steps of following these subjects and pursuing FDA approval."

Ivantis has also reported that the positive two-year results from the international HYDRUS II study were recently accepted into *Ophthalmology*, a leading journal in ophthalmology. The HYDRUS II study was presented in its entirety at the American Academy of Ophthalmology (AAO) Meeting in October 2014, and is the first level-one evidence MIGS study to show an increasing treatment effect from one to two years relative to the control group. According to the company, the HYDRUS II trial was designed to be highly similar to the HYDRUS IV trial, though the HYDRUS IV results alone will be the foundation of the efficacy analysis of the Hydrus device during the U.S. regulatory review process.

About the Hydrus device: The Hydrus™ Microstent, roughly the size of an eyelash, is placed through a minimally invasive, microsurgical procedure and is designed to reduce IOP by reestablishing the patient's natural outflow pathway. The Hydrus creates a large opening through the traditional source of flow blockage (known as the trabecular meshwork) and it dilates and scaffolds the conventional pathway (known as Schlemm's canal) through which fluid exits the eye. In addition to the HYDRUS II and HYDRUS IV trials, the Hydrus technology is also being studied internationally in both cataract and stand-alone glaucoma surgery settings in various types and severities of glaucoma. Over 2000 procedures have been performed as part of clinical studies or global registries.

About the HYDRUS IV study: The HYDRUS IV study is a prospective, multicenter, single masked, controlled randomized study in patients with mild to moderate glaucoma undergoing cataract surgery. The patients

were randomized 2:1 to Hydrus Microstent plus cataract surgery or cataract surgery alone, and will undergo follow-up evaluations at both the one and two year time points.

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, Ascension Health Ventures, Vertex Ventures, EDBI, Foresite Capital, GBS Ventures and MemorialCare Innovation Fund. More information can be found at www.ivantisinc.com.

Caution: In the United States, the Hydrus™ Microstent is limited by Federal (United States) law to investigational use only and is available only as an investigational device.

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