Ivantis Announces HYDRUS II Glaucoma Study Met Primary Endpoint In a Randomized Controlled Trial at Two Years

Results from Landmark International Study Show Hydrus™ Microstent Significantly Reduced Intraocular Pressure and Medication Use in Patients with Glaucoma Undergoing Cataract Surgery

IRVINE, Calif. - (BUSINESS WIRE) - 21 Oct 2014 - Ivantis, Inc., developer of the novel Hydrus™ Microstent, an investigational device designed to lower eye pressure in patients with open angle glaucoma, today announced that the international HYDRUS II trial met its primary endpoint by a wide margin. Results of the randomized, controlled study showed that the Hydrus Microstent, a minimally invasive glaucoma surgery (MIGS) device, significantly reduced intraocular pressure (IOP) and medication use in patients with open angle glaucoma undergoing cataract surgery 24 months post-operatively. The data were presented by Thomas W. Samuelson, MD in a paper presentation at AAO 2014, the annual meeting of the American Academy of Ophthalmology (AAO).

“HYDRUS II is the first randomized, controlled, multicenter trial to demonstrate the ability of a MIGS device to lower IOP (> 20% without meds) compared to cataract surgery alone at two years. It was the first trial to employ a “terminal washout”, designed to eliminate the confounding effects of topical medications in the assessment of IOP, which is vital to truly understanding the efficacy of a therapy,” said Thomas W. Samuelson, M.D., adjunct associate professor of ophthalmology at the University of Minnesota, a founding partner and attending surgeon at Minnesota Eye Consultants, and the medical monitor of the HYDRUS II study. “As a glaucoma surgeon, I am very encouraged by the 2 year data demonstrating excellent efficacy along with the safety that we have come to expect from the MIGS sector.”

“The clinically and statistically significant results of the HYDRUS II trial give us great confidence in the performance of the Hydrus device, not only in the short term, but also over time. This trial employed several rigorous standards and guidelines now in place for many of the U.S. pivotal trials for glaucoma, including our own ongoing U.S. pivotal HYDRUS IV trial,” said Dave Van Meter, president and CEO of Ivantis. “We intend to complete the enrollment for the HYDRUS IV trial in the first quarter of 2015, which is the next milestone in the process of gaining a larger body of level one evidence supporting the Hydrus technology.”

HYDRUS II Study Design

The prospective, multicenter, single-masked, randomized HYDRUS II clinical trial was designed to demonstrate the safety and efficacy of the Hydrus Microstent in lowering IOP in glaucoma patients undergoing cataract surgery. HYDRUS II enrolled 100 patients with open angle glaucoma at seven European eye hospitals. One-half of the patients received the Hydrus device plus cataract surgery (treatment group) and one-half received cataract surgery alone (control group). A total of 93 patients were available for follow up at two years. The primary endpoint of the trial was the proportion of patients per group who achieved a minimum of 20 percent drop in IOP at two years compared with pre-surgery IOP.

Prior to entering the study patients had, on average, an IOP of 19 and were taking two daily eye drops to control it. They were asked to stop taking their medications roughly 30 days prior to surgery to establish an unmedicated IOP. At the time of surgery, patients in each group had an average IOP without medications of 26, considered well above normal. Patients were then randomized to either the treatment group or control group and

medications were withheld following surgery. The study protocol recommended the IOP level at which medications should be re-administered to patients during the two year follow-up. At the end of two years, IOP medications were stopped for approximately 30 days to establish another unmedicated IOP and to isolate the effect of the Hydrus device.

HYDRUS II Study Results

At the two-year follow up period, 73 percent of the treatment group were medication free compared with 38 percent of the control group (p value 0.0008) – an improvement of 92 percent. At two years, following medication removal, 80 percent of the treatment group achieved a 20 percent or greater drop in IOP compared with 46 percent of the control group (p value 0.0008.). A 20 percent drop is considered clinically meaningful according to the American Academy of Ophthalmology (AAO)i. The rate of side effects was comparable in both groups, and vision was not affected by the addition of the Hydrus Microstent to the cataract surgery. Additionally, in a site-by-site analysis, the results across all seven centers were consistent with one another, which supports the reproducibility of the surgical technique and the validity of the overall results.

About Glaucoma

The World Health Organization (WHO) estimates that 32 million surgeries for cataracts will be performed globally by 2020; several million patients undergoing cataract surgery also have glaucoma. In the United States, more than 20 percent of the 3.5 million patients undergoing cataract surgery have a concurrent diagnosis of glaucoma.[ii] This represents approximately 700,000 patients each year in the United States who may be candidates for the investigational Hydrus treatment. Currently, antihypertensive eye drops are considered first-line therapy for glaucoma patients undergoing cataract surgery. However, adherence to treatment is as low as 50 percent after the first year,[iii] and the costs of these medications exceed $2.5 billion annually in the United States.

About Hydrus

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. Most often, glaucoma patients have both a blockage and a collapse of the natural outflow pathway. The Hydrus device has a dual mechanism of action – it creates a large opening through the traditional source of flow blockage, known as the "trabecular meshwork," and dilates and scaffolds the conventional pathway through which fluid exits the eye (known as Schlemm's canal).

Hydrus is being evaluated in glaucoma patients undergoing cataract surgery in the international HYDRUS II trial and in the ongoing pivotal HYDRUS IV trial in the United States. It also is being studied internationally in cataract surgery and in stand-alone glaucoma surgery.

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.

The Hydrus Microstent is not approved for sale and is available only under clinical investigation in the United States.

[i] Preferred Practice Pattern® Guidelines, Primary Open Angle Glaucoma, American Academy of Ophthalmology. 2006:page 12.

[ii] Tseng. Risk of fractures following cataract surgery in Medicare beneficiaries. JAMA. 2012;308(5):493-501.

[iii] Vrijens. Adherence to prescribed antihypertensive drug treatments: longitudinal study of electronically compiled dosing histories. BMJ. 2008;336(7653):1114-1117.

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