

## **Transcend Medical Completes Enrollment in Landmark Glaucoma Study Evaluating the CyPass® Micro-Stent**

*– Achievement of Milestone Brings Promising Glaucoma Therapy One Step Closer to FDA Review –*

MENLO PARK, Calif. — Feb 28, 2013 — Transcend Medical, Inc., a medical device company dedicated to developing minimally invasive glaucoma interventions for the ophthalmic surgeon, announced completion of enrollment in the COMPASS Clinical Study evaluating the CyPass Micro-Stent in combination with cataract surgery for patients with primary open-angle glaucoma.

“This is an important milestone in the field of glaucoma. The CyPass device is the first micro-invasive stent designed to enhance suprachoroidal outflow, a drainage pathway with untapped potential to reduce intraocular pressure (IOP). Implantation of the CyPass Micro-Stent is uniquely elegant and straightforward, and the clinical data generated by our colleagues in Canada and Europe over the last four years has been very promising,” said Dr. Steven Vold, Founder and CEO of Vold Vision (Fayetteville, AR) and Chairman of the COMPASS Steering Committee. “I am honored to be a member of the distinguished COMPASS investigational team, and we look forward to presenting the results upon study completion.”

One of the largest glaucoma surgery studies to date, COMPASS is a prospective, multicenter, randomized, controlled trial conducted at more than 20 sites in the United States. Over 500 glaucoma patients undergoing cataract surgery have been randomized to receive either the CyPass Micro-Stent during cataract surgery or to undergo cataract surgery alone. The primary effectiveness endpoint for the study is the proportion of eyes with  $\geq 20\%$  decrease in IOP from baseline to the medication-free 24-month postoperative examination.

With the completion of COMPASS enrollment, there are now more than 1,000 patients treated with the CyPass Micro-Stent in Transcend’s worldwide clinical development programs.

In the U.S., over 20% of patients undergoing cataract surgery have a concurrent diagnosis of glaucoma,<sup>1</sup> representing approximately 700,000 patients each year who may be candidates for the investigational treatment. Currently, antihypertensive eye drops are the first-line therapy for these glaucoma patients, although adherence to such treatments is as low as 50% after the first year.<sup>2</sup>

“Micro-invasive glaucoma surgery (MIGS) devices such as the CyPass Micro-Stent represent important advances as we try to address the problem of glaucoma. There is much need for new approaches in this field, and in recent years there has been significant progress at innovative companies like Transcend,” said Dr. H. Dunbar Hoskins, Jr., Clinical Professor, University of California, San Francisco (San Francisco, CA) and former executive vice president of the American Academy of Ophthalmology.

“Completion of COMPASS enrollment represents a tremendous effort by both the company and the investigational sites,” said Brian Walsh, President and CEO of Transcend Medical. “Our team has been laser-focused on enabling the CyPass Micro-Stent to be the next MIGS device available for FDA review. When the COMPASS study concludes, the results will provide an unprecedented level of data regarding the use of a glaucoma micro-stent in patients undergoing cataract surgery. We are excited to be moving this technology forward, as we believe the CyPass Micro-Stent has the potential to improve glaucoma management for millions of patients worldwide.”

### **About the CyPass® Micro-Stent\***

The CyPass Micro-Stent is the first micro-invasive glaucoma stent designed to reduce IOP by enhancing aqueous outflow to the suprachoroidal space, one of the eye’s natural, alternative drainage pathways. Implanted in the supraciliary space, the CyPass device bypasses the ciliary body by creating a stented micro-cyclodialysis and enhancing the same outflow system targeted by prostaglandin analogues, the most effective medical treatment for IOP. Targeting suprachoroidal outflow bypasses the trabecular meshwork and Schlemm’s canal — drainage paths that may be compromised in glaucomatous eyes. While the CE mark for the device was granted in 2008, the CyPass Micro-Stent is currently for investigational use only.

### **About Transcend Medical, Inc.**

Transcend Medical ([www.transcendmedical.com](http://www.transcendmedical.com)) is focused on the development of minimally invasive medical devices for the treatment of glaucoma, the leading cause of adult irreversible blindness. Over 4 million people in the U.S. and roughly 60 million worldwide are afflicted with the disease today, and the numbers are expected to grow to nearly 6 million in the U.S. and over 70 million worldwide by the year 2015.

**\*Caution:** Investigational Device. Limited by Federal (USA) law to investigational use.

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<sup>1</sup> Tseng. Risk of fractures following cataract surgery in Medicare beneficiaries. JAMA. 2012;308(5):493-501.

<sup>2</sup> Vrijens. Adherence to prescribed antihypertensive drug treatments: longitudinal study of electronically compiled dosing histories. BMJ. 2008;336(7653):1114-1117.