

Transcend Medical Announces Intent to File a PMA for the CyPass Micro-Stent

Transcend Medical announced its intent to file a pre-market approval (PMA) application with the FDA for the CyPass Micro-Stent, a novel microinvasive glaucoma surgical implant, according to a company news release. The company's recently completed COMPASS trial reportedly demonstrated sustained and consistent positive results through 2 years. Transcend Medical expects to file the PMA application with the FDA in the second half of 2015.

The COMPASS study's primary endpoint was met, demonstrating that implantation of the device in combination with cataract surgery resulted in a 20% or greater reduction in IOP from a medication-free baseline in a statistically significantly higher proportion of eyes compared to cataract surgery alone at both the 1- and 2-year medication-free postoperative examinations. In addition, all secondary endpoints showed statistically significantly greater effectiveness of the CyPass Micro-Stent plus cataract surgery versus cataract surgery alone. Along with the device's effectiveness, safety was rigorously monitored over the 2-year follow-up period.

"The CyPass Micro-Stent represents the next wave of innovation in the [microinvasive glaucoma surgery] implant category," Steven Vold, MD, chair of the COMPASS Steering Committee and one of the lead investigators for the study, said in the company news

release. "It is encouraging to see the COMPASS results validated through such a large, robust pivotal study. With an elegant, straightforward implantation procedure coupled with these positive clinical outcomes, the CyPass Micro-Stent is positioned to provide a valuable new therapeutic option for ophthalmologists treating their cataract patients suffering from glaucoma."

The COMPASS study was a prospective, multi-center, randomized, controlled trial conducted at more than 20 sites throughout the United States under an Investigational Device Exemption as part of the PMA requirements for the device. Over 500 patients with mild to moderate glaucoma undergoing cataract surgery were randomized to either receive the CyPass Micro-Stent after cataract surgery or undergo no further intervention.

"We are very pleased with the results of the COMPASS trial," Brian Walsh, president and CEO of Transcend Medical, said in the news release. "We are committed to a rigorous, evidence-based approach to evaluating the CyPass Micro-Stent, and the COMPASS study is a testament to this mission. We believe the CyPass technology has the potential to help the millions of patients who suffer from glaucoma worldwide, and we look forward to FDA's review of our PMA submission."

Dr. Vold is a consultant to and investigator for Transcend Medical.

Rhopressa Phase 3 Trial Misses Primary Endpoint

Aerie Pharmaceuticals reported in April that its phase 3 registration trial, Rocket 1, did not meet the primary efficacy endpoint of demonstrating noninferiority of IOP lowering for once-daily Rhopressa compared to twice-daily timolol, according to a company news release. Rhopressa, a novel once-daily, triple-action eye drop, is being tested for its ability to lower IOP in patients with glaucoma or ocular hypertension. The drug reportedly demonstrated noninferiority compared to timolol for patients in the study with IOPs below 26 mm Hg at all nine measured time points and numerical superiority over timolol at the majority of measured time points.

Rhopressa did not meet its primary efficacy endpoint based upon IOP measurements at the end of weeks 2 and 6 and day 90. The Rocket 1 study included 182 patients in the Rhopressa once-daily arm and 188 patients in the timolol twice-daily arm. The baseline IOPs ranged

from above 20 mm Hg to below 27 mm Hg. The results showed a slight loss of efficacy at week 6 and day 90. In the Rhopressa arm, 36 patients (approximately 20%) showed signs of loss of efficacy during the study. The primary adverse event was hyperemia, which was experienced by approximately 35% of the Rhopressa patients, of which 80% was reported as mild.

"We are obviously disappointed that we missed the primary endpoint for Rocket 1," Vicente Anido Jr, PhD, chairman and CEO of Aerie, said in the news release. "We expected Rhopressa to demonstrate better performance based on the results we saw in the previous phase 2b studies. We look forward to our Rocket 2 efficacy results expected in the third quarter and 12-month safety results expected by the end of 2015. Rocket 2 results are expected to inform our future strategies, including the potential need for an additional Rhopressa phase 3 registration trial. In addition, we are well prepared to commence the quadruple-action Roclatan phase 3 trials later in 2015. As of the end of the first quarter 2015, we had over \$179 million of cash and

investments on our balance sheet and are well financed to proceed with our key strategies.”

More recently, the law firm of Kessler Topaz Meltzer & Check announced that a shareholder class action has been filed against Aerie on behalf of purchasers of the company's common stock between August 6, 2014, and April 23, 2015, inclusive (the “class period”). The complaint alleges that, throughout the class period, Aerie and certain of its executive officers made a series of false and misleading statements and/or failed to disclose material adverse information about the future prospects for Rhopressa.

Clearside Biomedical and Santen Announce Research Collaboration in Glaucoma

Clearside Biomedical and Santen announced the expansion of their research collaboration to include the field of glaucoma, according to a news release. The two companies have been working together since January 2013 to develop drugs to treat diseases affecting the retina and choroid that can eventually lead to blindness. The expanded collaboration will now study the use of Clearside's proprietary micro-injector to deliver sustained IOP-lowering medications.

Glaukos Files Registration Statement for Proposed Initial Public Offering

Glaukos has filed a registration statement with the Securities and Exchange Commission relating to the proposed initial public offering of its common stock, according to a news release. The number of shares to be offered and the price range for the proposed offering have not yet been determined. In connection with the proposed initial public offering, Glaukos has applied to list its common stock on The New York Stock Exchange under the symbol “GKOS.” J.P. Morgan, BofA Merrill Lynch, and Goldman, Sachs are reportedly acting as joint book-running managers for the offering, and William Blair and Cantor Fitzgerald are acting as comanagers for the offering.

Canaloplasty Pioneer Receives Award

Norbert Körber, MD, recently received the Glaucoma Research Award from the German Federate Eye Association, a patient advocacy group, in recognition of his pioneering work in the field of canaloplasty. An

Online Survey Results March/April 2015

If the angle can still be occluded after laser peripheral iridotomy, do you consider performing argon laser iridoplasty?

Yes	75%
No	25%

How often do you perform gonioscopy?

Regularly	81.25%
Sometimes	18.75%
Rarely	0
Never	0

early adopter of the procedure, Dr. Körber was involved in one of the first landmark trials of canaloplasty—a prospective multicenter trial carried out at 15 clinical sites in the United States, Great Britain, and Germany in 2005.¹ According to Dr. Körber, the 3-year data from that trial validated the potential benefits of the procedure by demonstrating a significant and sustained IOP reduction and decreased need for medication in adult patients with open-angle glaucoma. It also confirmed the excellent short- and long-term safety profile of the procedure. The results of Dr. Körber's own subset of patients reportedly showed only a slight increase in mean IOP and medication use 5 years postoperatively, with the results sustained well past 5 years (unpublished data, 2014).

A quality-of-life study conducted by Dr. Körber in collaboration with the University of Würzburg in 2012 found that canaloplasty patients (n = 176) were more satisfied with their surgery than those who underwent a trabeculectomy (n = 152).² The canaloplasty patients were happier and less anxious about the surgery than the trabeculectomy patients (84% vs 51%). The stress induced by the postoperative care was statistically significantly lower after canaloplasty (14% vs 46%), and there were also fewer postoperative complaints and less interference with daily activities for patients in the canaloplasty group. The survey also found that fewer revision surgeries were needed after canaloplasty (8% vs 35%) and that 57% of the patients who had undergone canaloplasty were highly satisfied with the results of the surgery in contrast to 41% of patients after trabeculectomy. ■

1. Lewis RA, Wolff KV, Tetz M, et al. Canaloplasty: three-year results of circumferential viscodilation and tensioning of Schlemm's canal using a microcatheter to treat open-angle glaucoma. *J Cataract Refract Surg*. 2011;37:682-690.
2. Salgado JP, Sauer J, Körber NJ, et al. Quality of life in glaucoma surgery: canaloplasty versus trabeculectomy. Poster presented at: The European Glaucoma Society; June 18, 2012; Copenhagen, Denmark. <http://www.oic.it/~egscopenhagen2012/posters/june18/P1.33/poster.pdf>.