

Microplasmin Meets Primary Endpoint in Second Phase III Trial in VMA, Confirms Positive Findings of First Trial

Data Presented at ASRS Confirm Previous Phase III Findings and Microplasmin's Potential to Transform the Treatment of Retinal Disorders

Leuven, Belgium – 1 September, 2010 – ThromboGenics NV (Euronext Brussels: THR), a biopharmaceutical company focused on the discovery and development of innovative treatments for eye disease, vascular disease and cancer announces that its second Phase III trial evaluating microplasmin for the non-surgical treatment of vitreomacular adhesion (VMA) has met its primary endpoint. Importantly, the trial also confirmed the positive results seen in the first Phase III trial with microplasmin. The results of the second Phase III trial (TG-MV-007) were presented for the first time at the American Society of Retina Specialists (ASRS) Annual Meeting by Dr. J. Michael Jumper (West Coast Retina and Medical Group and California Pacific Medical Center, California, USA). The trial recruited 326 patients at 48 centers in Europe and the U.S.

The detailed positive results from the first Phase III trial in the microplasmin MIVI-TRUST program (TG-MV-006) were presented at the World Ophthalmology Congress in Berlin in June 2010. The pooled results of both trials will be presented at the upcoming EURETINA (European Society of Retina Specialists) Congress in Paris, France, on September 4 by Prof. Peter Stalmans (University Hospitals Leuven, Belgium).

In his presentation at ASRS, Dr. Jumper highlighted that the TG-MV-007 study had met its primary endpoint, with 25.3% of the 245 microplasmin treated patients achieving resolution of their VMA at 28 days, compared to 6.2% of the 81 patients who received a placebo injection, a highly statistically significant result ($p=0.001$). In patients without epiretinal membrane, microplasmin was shown to be even more effective with 34.5% of patients seeing resolution of their VMA at 28 days, compared to 6.4% of placebo treated patients. Epiretinal membrane is a layer of scar tissue which builds up on the macula, making it more difficult to achieve resolution of VMA without surgical intervention. Epiretinal membrane can be easily identified using Optical Coherence Tomography (OCT).

The TG-MV-007 trial also showed that microplasmin was highly effective in treating patients who had been diagnosed with full thickness macular hole (FTMH). In this group, 36.7% of the 49 patients saw closure of their FTMH at 28 days following a single 125 μ g injection of microplasmin, without the need for a vitrectomy. This compares with 6.7% of the 15 patients in the placebo group ($p=0.028$). These positive results are in line with what was achieved in this patient group in the TG-MV-006 study.

The TG-MV-007 study also evaluated the visual acuity (VA) of patients. This analysis showed that at the end of the study 22.0% of the microplasmin treated patients had achieved at least a 10 letter (2 lines) improvement in VA without the need for vitrectomy. This compares to only 11.1% of the patients who received a placebo injection ($p<0.05$). Within the microplasmin treated population, 9% of patients achieved a 15 letter (3 lines) improvement in their visual acuity without the need for vitrectomy, a level of nonsurgical improvement that was not seen in any of the patients who received placebo ($p<0.005$). In addition, microplasmin treated patients showed an improved Quality of Life when compared

to placebo, based on the VFQ-25 (National Eye Institute Visual Functioning Questionnaire) results.

The TG-MV-007 study confirmed that microplasmin was generally safe and well tolerated. Importantly, consistent with the findings of the TG-MV-006, there was no evidence of an increased risk of retinal tear or detachment.

Dr. Patrik De Haes, CEO of ThromboGenics, commented, “I am very pleased that the results from the TG-MV-007 study announced yesterday have confirmed the positive findings of the first Phase III trial and clearly show microplasmin’s potential to make a significant impact on the treatment of vitreoretinal disorders. Over the next several months, key investigators who participated in the studies will be presenting the exciting data from the overall MIVI-TRUST program to the global retina community at a number of major international ophthalmology congresses. Given the success of the overall Phase III clinical program, I am extremely confident that microplasmin has the potential to provide both patients and retina specialists with a highly attractive treatment option for a broad range of retinal disorders.”

Dr. J. Michael Jumper, commenting on his presentation at the ASRS, said, “These results confirm microplasmin’s potential to treat patients with macular disease caused by vitreous traction, including full thickness macular hole (a condition which currently requires major eye surgery to prevent irreversible vision loss), with a single intravitreal injection, a very appealing option when compared to surgery.”

16th Annual Gertrude D. Pyron Award for Outstanding Achievement in Retina Research

Dr. Julia Haller (Ophthalmologist-in-Chief, Wills Eye Institute, and Professor and Chair of Department of Ophthalmology of Thomas Jefferson University, Philadelphia), was presented with the 16th Annual Gertrude D. Pyron Award for Outstanding Achievement in Retina Research at ASRS. At the meeting, she chose to discuss microplasmin as a treatment option for retinal diseases in the Pyron Lecture entitled, “Ties That Bind: The Vitreo-Retinal Relationship.” The lecture, which took place on August 29, centered on the positive results of the microplasmin Phase III program, with particular focus on the wealth of new information about the vitreoretinal interface that the MIVI-TRUST program has generated and its implications for the vitreoretinal surgeon.

Notes to Editors

About Focal Vitreomacular Adhesion (VMA)

Focal vitreomacular adhesion is a condition in which the vitreous gel, in the center of the eye, has an abnormally strong adhesion to the macula, the center of the retina at the back of the eye. Vitreomacular adhesion plays a key role in numerous back of the eye conditions, such as macular hole and some forms of macular edema. Vitreomacular adhesion is also associated with a worse prognosis in certain major eye conditions, including Diabetic Retinopathy and Age-related Macular Degeneration (AMD).

About Macular Hole

Focal vitreomacular adhesion can lead to macular hole, where the traction from the vitreomacular adhesion actually pulls off a piece of the macula (the part of the retina responsible for central vision). If not treated with major eye surgery called a vitrectomy,



which involves using suction to remove the vitreous from the eye, macular hole can lead to irreversible, central blindness. While vitrectomy is generally effective in closing macular holes, it is an invasive procedure and a proportion of patients experience side-effects. These include alteration of vision, bleeding, retinal detachment and development of glaucoma and cataracts. Therefore, a nonsurgical treatment option for such patients could be an important breakthrough in the way macular hole patients are treated.

The MIVI-TRUST Program

The microplasmin Phase III program, referred to as MIVI-TRUST (Microplasmin for IntraVitreous Injection-Traction Release without Surgical Treatment), consists of two multi-center, randomized, placebo controlled, double-masked trials. These trials are designed to evaluate a single dose of 125µg microplasmin versus placebo in the intravitreal treatment of patients with symptomatic focal vitreomacular adhesion (VMA). The primary endpoint of both trials is the non-surgical resolution of focal vitreomacular adhesion one month after a single injection of microplasmin. This endpoint is assessed using optical coherence tomography (OCT). The MIVI-TRUST program is the largest interventional clinical program ever performed to specifically evaluate the vitreoretinal interface in patients with retinal disorders. In total, over 650 patients were enrolled in these trials, which were held across 90 centers in 7 countries.

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About ThromboGenics

ThromboGenics is a biopharmaceutical company focused on the discovery and development of innovative medicines for the treatment of eye disease, vascular disease and cancer. The Company's lead product microplasmin has completed two Phase III clinical trials for the non-surgical treatment of retinal disorders. Microplasmin is also being evaluated in Phase II clinical development for additional vitreoretinal conditions. In addition, ThromboGenics is developing novel antibody therapeutics in collaboration with BioInvent International; these include TB-402 (anti-Factor VIII), a long acting anti-coagulant in Phase II, and TB-403 (anti-PIGF) in Phase Ib/II for cancer in partnership with Roche.

ThromboGenics is headquartered in Leuven, Belgium. The Company is listed on Eurolist by Euronext Brussels under the symbol THR. More information is available at www.thrombogenics.com.



Important information about forward-looking statements

Certain statements in this press release may be considered “forward-looking”. Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason. Additional information concerning risks and uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the Company’s Annual Report.