

## **ThromboGenics Presents Positive Pooled Results from the MIVI-TRUST Phase III Program, Confirming Microplasmin's Potential to Transform the Treatment of Retinal Disorders**

### **Data Presented at EURETINA Highlight the Attractive Characteristics of this Novel Potential Treatment Option for Retinal Disorders**

**Leuven, Belgium – 6 September, 2010** – ThromboGenics NV (Euronext Brussels: THR), a biopharmaceutical company focused on the discovery and development of innovative treatments for eye disease, cardiovascular disease and cancer, announces that the pooled results from the successful microplasmin MIVI-TRUST Phase III program were presented today at the EURETINA (European Society of Retina Specialists) Congress in Paris, France. The MIVI-TRUST program is the largest interventional clinical program ever performed to specifically evaluate the vitreoretinal interface in patients with retinal disorders, recruiting a total of 652 patients at 90 centers across the U.S. and Europe.

The pooled results of the TG-MV-006 and TG-MV-007 Phase III trials were presented by Prof. Peter Stalmans (University Hospitals Leuven, Belgium). These results demonstrate the potential of microplasmin to transform the treatment of a range of retinal disorders.

The Phase III program showed that microplasmin:

- Was successful in resolving vitreomacular adhesion (VMA)
- Was able to cure full thickness macular hole (FTMH) without the need for surgery
- Delivered an improvement in the vision of patients without the need for surgery
- Was safe and well tolerated

Both the TG-MV-006 and TG-MV-007 trials met the primary endpoint, achieving a statistically significant improvement in the resolution of VMA. The pooled results from the MIVI-TRUST program showed that 26.4% of the 465 microplasmin treated patients achieved resolution of their VMA at 28 days, compared to 10.2% of the 182 patients who received a placebo injection, a highly statistically significant result ( $p=0.000002$ ).

In patients without epiretinal membrane, microplasmin was shown to be even more effective, with 37.4% of 270 patients achieving nonsurgical resolution of their VMA at 28 days, compared to 14.3% of 119 placebo treated patients ( $p=0.000003$ ). 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 MIVI-TRUST program's pooled results also highlighted microplasmin's impressive effect in patients diagnosed with FTMH. In this group, 40.6% of the 106 patients saw closure of their FTMH at 28 days following a single 125 $\mu$ g injection of microplasmin without the need for a vitrectomy. This compares with 10.6% of the 47 patients in the placebo group ( $p=0.00015$ ). The closure of FTMH also led to microplasmin treated patients experiencing a significant improvement in their visual acuity (VA) compared to baseline.

Prof. Stalmans also presented an analysis of the pooled visual acuity data from the Phase III program. This showed that at the end of the six month study period, 23.7% 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 11.2% of the patients who received a placebo injection ( $p=0.0002$ ). Within the microplasmin treated population, 9.7% of patients achieved a 15 letter (3 lines) improvement in their visual acuity without the need for vitrectomy, compared to just 3.7% of the placebo patients ( $p=0.01$ ). In addition, microplasmin treated patients showed an improved Quality of Life when compared to placebo, based on the VFQ-25 (the National Eye Institute Visual Functioning Questionnaire) results.

The pooled results also confirmed that microplasmin was generally safe and well tolerated. There was no evidence of an increased risk of retinal tear or detachment.

**Dr. Patrik De Haes, CEO of ThromboGenics, commented,** “The successful completion and reporting of our 652 patient Phase III program with microplasmin in just 20 months demonstrates ThromboGenics’ highly effective drug development capabilities. The pooled data presented today clearly show that microplasmin could make a significant difference to the treatment of vitreoretinal disorders. The results from these pivotal trials will form the central part of the packages that we plan to submit to the FDA and EMA by mid 2011 to support our applications for marketing approval. Given the success of the overall Phase III clinical program and our plans to market microplasmin ourselves both in the U.S. and Europe, we are now gearing up our pre-marketing activities and our commercial organization. Based on these exciting results and our discussions with many leading retinal specialists, I am convinced that microplasmin has the potential to become a highly attractive treatment option for a broad range of retinal disorders.”

**Prof. Peter Stalmans, commenting on his presentation at EURETINA, said,** “I am delighted to have presented these pooled results for the first time. Based on these exciting Phase III results and my own personal experience, I have little doubt that microplasmin will quickly become an important treatment option for patients with a range of retinal disorders, including macular hole. The benefits of this simple one-off injection are very appealing, when compared to surgery, to both patients and retina specialists.”

## 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](http://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.*