

## **ThromboGenics Completes Patient Enrolment in US Phase III Trial of Microplasmin for the Non-Surgical Treatment of Eye Disease**

### **Enrolment of 326 patients completed ahead of schedule**

**Leuven, Belgium – 24 September, 2009** – 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 today that it has completed the enrolment of the US Phase III trial evaluating microplasmin for the non-surgical treatment of eye disease. The trial TG-MV-006 has completed enrolment with a total of 326 patients several months ahead of schedule. The second Phase III study with microplasmin, TG-MV-007, which is recruiting patients in the US and Europe is due to complete enrolment in the first half of 2010 as planned. Enrolment completion in this study means that ThromboGenics is a step closer to becoming a profitable, integrated Company focused on cutting edge ophthalmic medicines.

Microplasmin's Phase III program is referred to as the MIVI-TRUST (Microplasmin for IntraVitreous Injection-Traction Release without Surgical Treatment) program. This program involves two clinical trials, which are taking place in the United States (TG-MV-006 trial) and Europe and the United States (TG-MV-007 trial). Both of the MIVI-TRUST trials are multi-center, randomized, placebo controlled, double-masked trials which are evaluating 125µg of microplasmin versus placebo in the intravitreal treatment of patients with focal vitreomacular adhesion.

The initial indication for both of the Phase III microplasmin trials is the non-surgical treatment of focal vitreomacular adhesion. Focal vitreomacular adhesion is a condition in which the vitreous gel, in the center of the eye, has an abnormally strong adhesion to the retina at the back of the eye. Vitreomacular adhesion is thought to play a key role in numerous back of the eye conditions such as macular hole formation, and some forms of macular edema. Vitreomacular adhesion is also associated with a much poorer prognosis in certain major eye conditions, including diabetic retinopathy and Age-related Macular Degeneration (AMD).

The primary endpoint of both trials is the non-surgical resolution of focal vitreomacular adhesion after one month. This anatomical endpoint is being measured and recorded using optical coherence tomography (OCT) which provides images that can clearly show the separation of the vitreous from the retina. OCT is a very sensitive and specific method for detecting the resolution of focal vitreomacular adhesion. ThromboGenics has used both OCT and ultrasound technology in previous studies evaluating microplasmin in eye disease. Based on this experience and discussions with the FDA, OCT was selected as the main assessment technique for the Phase III program as it provides results which have greater clinical relevance. In addition to the primary endpoint, the Phase III trials will evaluate additional measures of efficacy as well as safety, assessed at various time periods over the six month study period.

It is expected that the results from the TG-MV-006 study will be presented by mid 2010.

**Dr. Patrik De Haes, CEO of ThromboGenics commented,** "We are very pleased to announce that we have completed enrolment of the US pivotal Phase III trial for microplasmin months ahead of schedule. Microplasmin is key to the success of our ophthalmic focused strategy and the speed at which patients have been recruited is very



encouraging. Today's announcement brings us a step closer to potentially changing the way a number of important eye conditions are treated, as well as bringing us closer to our key aim of becoming a profitable, integrated business focused on cutting edge ophthalmic medicines. We very much look forward to announcing the results of this trial by the middle of next year and I am confident that ThromboGenics will continue to deliver on the milestones needed to build a strong, successful and profitable Company."

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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 is in Phase III clinical development for the non-surgical treatment of back of the eye diseases. Microplasmin is also being evaluated in Phase II clinical development for additional vitreoretinal indications. 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, and TB-403 (anti-PIGF) for cancer.

ThromboGenics has built strong links with the University of Leuven and the Flanders Institute for Biotechnology (VIB) and has exclusive rights to certain therapeutics developed at these institutions. 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.*