

**Regulated Information**

**Disclosure in accordance with the law of May 2, 2007**

**ThromboGenics NV**

**Business Update**

**Leuven, Belgium – 4 November, 2009** – ThromboGenics NV (Euronext Brussels: THR), a biopharmaceutical company focused on innovative medicines for eye disease, vascular disease and cancer, is today issuing a business update for the period ending 30 September, 2009.

**Patrik De Haes, CEO of ThromboGenics, said:**

“ThromboGenics’ clinical development programs have continued to make significant progress. We are very happy to have completed patient enrolment for the US Phase III study with microplasmin and recruitment in our second Phase III trial is continuing to make excellent progress. Microplasmin is central to our aim of building a successful integrated company focused on cutting edge ophthalmic medicines, that is positioned to deliver significant shareholder value.

We have also recently completed patient recruitment of a Phase II study with TB-402, assessing it as a DVT prophylactic in patients undergoing knee replacement, ahead of schedule. Our experience with TB-402 suggests that this long acting product has the potential to be an important new entrant into the anticoagulant market making it an attractive out-licensing opportunity. Our partnership with Roche for the novel anti-cancer antibody TB-403 continues to make good progress, with results from the Phase Ib trial to be presented later this month at the American Association for Cancer Research conference.”

**Financial Update**

- ThromboGenics achieved revenues of €3.7 million over the first nine months of 2009, the majority of which came from out-licensing. R&D expenses were €12.6 million during this nine month period. In addition €10.4 million of expenses related to the microplasmin Phase III clinical program have been capitalized over the first nine months of this year.
- As of September 30, 2009, ThromboGenics had €43.1 million in cash and cash equivalents. This compares to €60.9 million on September 30, 2008 and €58.9 million on December 31, 2008.



## Business Highlights

### Clinical Highlights

**Microplasmin – Back of the Eye Disease: Phase III clinical program to evaluate non-surgical treatment of patients with vitreomacular adhesion.**

- **Phase III program continues to progress well, with enrolment completed for TG-MV 006 and on track for TG-MV 007**

In September, ThromboGenics announced the completion of patient recruitment in the US trial (TG-MV-006) of the Phase III program with microplasmin for the non-surgical treatment of vitreomacular adhesion (a back of the eye condition). The trial recruited a total of 326 patients ahead of schedule and we anticipate reporting the results from this study by mid 2010, after a 6 month follow up period.

The second Phase III study with microplasmin, TG-MV-007, which is recruiting 320 patients in Europe and the US, is progressing well and we expect complete enrolment within the first quarter of 2010 and results of this study near the end of 2010.

This Phase III program, referred to as the MIVI-TRUST (Microplasmin for IntraVitreous Injection-Traction Release without Surgical Treatment) program, comprises two clinical trials, taking place in the United States (TG-MV-006 trial) and a second combined European and US study (TG-MV-007 trial). The indication for both of these Phase III microplasmin trials is the non-surgical treatment of focal vitreomacular adhesion. Vitreomacular adhesion is a condition in which the vitreous has an abnormally strong adhesion to the retina at the back of the eye. These adhesions can cause vessel and retinal distortion, which results in deterioration in the patient's vision. Both of these trials use the 125µg dose of microplasmin.

**Microplasmin – Diabetic Retinopathy: Phase II trial to evaluate microplasmin for the treatment of Diabetic Macular Edema (DME).**

- **Results from the Phase IIa trial presented at the American Society of Retina Specialists (ASRS) Conference in New York**

In October 2009, ThromboGenics announced results from the Phase II trial of microplasmin intravitreal injection for treatment of DME (MIVI II DME). The trial showed that microplasmin was safe and well tolerated and that microplasmin is able to non-surgically resolve vitreomacular adhesion in some DME patients. The data from this trial were presented at the ASRS Conference in New York on 3 October, 2009 by Professor Peter Stalmans, University Hospitals Leuven, Belgium.

The MIVI II DME trial was designed to be the initial step in evaluating microplasmin in patients with diabetes, a group which is more prone to eye disease, and specifically diabetic retinopathy. ThromboGenics will finalize the next step in the development plan for microplasmin in this patient population once the results from the first Phase III trial (TG-MV-006) are reported. These results will provide significant additional data that will help ThromboGenics to refine the development plans for microplasmin in patients with diabetic retinopathy.



## **TB-402 – Phase II trial assessing the long-acting anticoagulant TB-402 for the prophylaxis of Deep Vein Thrombosis (DVT) following orthopedic surgery.**

- **Phase II trial has completed recruitment of 315 patients ahead of schedule**
- **Results are expected in the second quarter of 2010**

In October, ThromboGenics announced the completion of patient recruitment for the Phase II trial of TB-402 ahead of schedule. TB-402 is a novel, long acting anticoagulant that is being developed for the prevention of deep vein thrombosis (DVT) following orthopedic surgery. It is anticipated that the results of this study, which has recruited 315 patients, will be presented in the second quarter of 2010.

TB-402 has the potential to be a very important new entrant into the anticoagulant market. TB-402 is a recombinant human monoclonal antibody that partially inhibits Factor VIII, a key component of the coagulation cascade. This novel mode of action is expected to reduce the risk of undesirable bleeding events, even at high doses, as well as the need for patient monitoring. These are the two main drawbacks associated with current anticoagulant therapy. In addition, TB-402 is a long-acting agent, which means it could be given as a single dose to prevent the development of DVT in patients undergoing surgery. This would be an attractive option, as all current anticoagulant treatment options require daily treatment for up to several weeks.

ThromboGenics and its partner BioInvent plan to out-license TB-402 for its later stage development and commercialization. This out-licensing strategy is driven by the large sales potential of the product and the broad range of prescribers that could use an anticoagulant with TB-402's unique profile.

## **TB-403 (RG7334) – Novel anti-cancer agent partnered with Roche**

- **TB-403 Phase Ib results to be presented at the American Association for Cancer Research (AACR) Conference**
- **ThromboGenics continues to build a strong relationship with Roche**

The clinical development of TB-403 is progressing as planned and the results of a Phase Ib trial are to be presented at the AACR conference in Boston, MA USA on **November 15-19, 2009**. The Phase Ib trial was designed to assess TB-403's tolerability, pharmacokinetics and pharmaco-dynamics in patients with advanced cancer.

In June 2008, ThromboGenics and its co-development partner BioInvent signed a strategic alliance deal with Roche for its novel anti-cancer agent, TB-403 (anti-PIGF). In January, 2009, ThromboGenics and BioInvent received their first success fee from Roche based on the successful transfer and implementation of technology and process development for TB-403 production. ThromboGenics received €3 million of the overall €5 million success fee.

## **Corporate Update**

**ThromboGenics is Shortlisted for “Biotech Company of the Year” and “Licensing Deal of the Year” at the Scrip Awards 2009**



- In September 2009, ThromboGenics was shortlisted for “Biotech Company of the Year” and “Licensing Deal of the Year” at the Scrip Awards 2009. The Biotech Company of the Year award recognizes the progress and achievement a biotech company has made within the last twelve months. The Licensing Deal of the Year award acknowledges the achievement of a Company in signing a licensing deal that has both monetary and strategic benefits to all parties. The awards ceremony will take place on November 18, 2009 in London.
- In October 2009, ThromboGenics announced that it raised €0.6 million as the result of the exercise of warrants. 90.000 shares were created and are now listed on Euronext Brussels. As a result of this exercise of warrants, ThromboGenics has 26.417.789 shares outstanding.

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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 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, 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***

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*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.*