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ThromboGenics

## **Positive Results from Phase II VTE Prophylaxis Study with TB-402 (Anti-Factor VIII) Presented at the 21<sup>st</sup> Int. Congress on Thrombosis in Milan, Italy**

### ***Study demonstrates TB-402 superior antithrombotic activity to enoxaparin***

**Lund, Sweden and Leuven, Belgium – 9 July 2010** – BioInvent International AB (OMXS: BINV) and ThromboGenics NV (Euronext Brussels: THR) announce that the positive results from a Phase II trial of TB-402 (Anti-Factor VIII antibody) were presented at the 21<sup>st</sup> International Congress on Thrombosis (ICT) in Milan, Italy yesterday. TB-402 is a novel, long acting anticoagulant that is being developed as a single injection for the prevention of venous thromboembolism (VTE) following orthopaedic surgery.

The data were presented by Professor Peter Verhamme (University of Leuven, Belgium) in a presentation entitled, "Single intravenous administration of TB-402 for the prophylaxis of VTE after total knee replacement surgery." The Phase II results showed the superior antithrombotic activity of TB-402, when compared to enoxaparin (Lovenox<sup>®</sup>: sanofi-aventis). The study showed that the two drugs had comparable safety. Enoxaparin is currently the standard treatment to prevent VTE in this setting. VTE encompasses both deep venous thrombosis (DVT) and pulmonary embolism (PE).

The Phase II trial was a multicenter, dose-escalating, randomised, open-label trial, evaluating TB-402 against enoxaparin for the prophylaxis of VTE after knee surgery. All patients received enoxaparin 40mg pre-operatively. Post operatively, patients were randomized in a sequential cohort design to one of three doses of TB-402 (0.3mg/kg, 0.6mg/kg or 1.2mg/kg) or enoxaparin 40mg (3:1; n=75 per group). The study enrolled a total of 316 patients across 30 centers in Europe.

TB-402 was administered as a single intravenous bolus injection 18–24 hours after orthopaedic surgery, whereas enoxaparin was given as a 40mg subcutaneous injection every day for a period of at least 10 days. The primary efficacy endpoint was based on measuring all occurrences of VTE in patients by Day 7-11, whether they were symptomatic or asymptomatic. The primary safety endpoint was the number of patients with major or clinically relevant non-major bleeding from randomisation until the end of the study at 3 months.

Professor Verhamme presented the pooled data for the TB-402 treated group, which showed that 47 out of 218 (or 22%) patients experienced VTE; this compares to the enoxaparin treated group, where 30 out of 77 (or 39%) patients experienced VTE ( $p < 0.05$ ). The difference of reduction in VTE between the two groups is statistically significant. The study also showed that TB-402 and enoxaparin had a similar safety profile.

**Svein Mathisen, CEO of BioInvent, commented,** "We are pleased to have Phase II results for TB-402 presented at this internationally recognized event, reinforcing the unique profile of this drug candidate which we expect to generate interest from pharmaceutical partners. We are excited by the opportunity that TB-402 provides in the anticoagulation marketplace due to its attractive dosing

opportunities and half life and the potential benefits this will provide for patients and healthcare providers alike.”

**Patrik De Haes, CEO of ThromboGenics, also commented,** “We are very pleased by Professor Verhamme’s presentation of the exciting TB-402 Phase II data at this important conference. VTE is a major clinical problem that carries considerable costs both to patients and healthcare providers, and we are very encouraged that TB-402 has demonstrated such an attractive profile compared to the current gold standard. These data have reinforced our view that a product that is able to reduce the incidence of VTE significantly in just a single post-operative injection could represent an exciting opportunity for a potential partner and allow us to bring TB-402 to market.”

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#### **Notes to Editors:**

##### **About TB-402**

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 be an effective and safe treatment alternative with less need for patient monitoring. 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 simple approach to prophylaxis would be an attractive option, as all current anticoagulant treatment options require daily treatment for up to several weeks.

##### **About Deep Vein Thrombosis (DVT)**

DVT is caused when a blood clot forms in a deep vein, most commonly in the deep veins of the lower leg. DVT is a major public health issue and it is estimated that in the U.S. alone, more than 600,000 patients are treated for venous thromboembolisms (VTE) such as DVT or pulmonary embolism (PE) each year.<sup>1</sup> Moreover, DVT and PE together may be responsible for more than 100,000 deaths in the U.S. each year.<sup>2</sup>

It is estimated that by 2015, 1.4 million patients will undergo knee replacement and 600,000 patients will undergo hip replacement in the U.S. if current trends persist.<sup>3</sup> Patients undergoing hip replacement or knee surgery are particularly at risk of developing DVT and all patients are therefore treated with anticoagulants prophylactically in order to reduce the risks of blood clots. The annual sales of anticoagulants worldwide are over \$5 billion. Nevertheless, available anticoagulants are still inconvenient and associated with an increased risk of bleeding. Improved anticoagulants are therefore required. In particular, agents that allow for improved ease of administration (without requirement for daily dosing and frequent dose adjustment) would fill a significant unmet need.

##### **About BioInvent**

BioInvent International AB, listed on the NASDAQ OMX Stockholm (BINV), is a research-based pharmaceutical company that focuses on developing antibody drugs. The Company currently has four clinical development projects within the areas of thrombosis, cancer and atherosclerosis. The Company has signed various strategic alliances to strengthen the product pipeline and increase the likelihood of success. These partners include Genentech, Human Genome Sciences, Roche and ThromboGenics.

The company’s competitive position is underpinned by an in substance patented antibody development platform. The scope and strength of this platform is also utilised by partners, such as Bayer HealthCare, Daiichi Sankyo, Mitsubishi Tanabe, UCB and XOMA.

More information is available at [www.bioinvent.com](http://www.bioinvent.com).

##### **About ThromboGenics**

ThromboGenics is a biopharmaceutical company focused on the discovery and development of innovative medicines for the treatment of eye disease. The Company’s lead product Microplasmin has completed its first Phase III clinical trial 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

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<sup>1</sup> Barclays Capital Equity Research Report on New Anticoagulants, August 5, 2009

<sup>2</sup> “The Surgeon General’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism,” September 15, 2008, p.1.

<sup>3</sup> “Changes in Surgical Loads and Economic Burden of Hip and Knee Replacements in the US: 1997-2004,” Sunny Kim, Arthritis & Rheumatism (Arthritis Care & Research), April 15, 2008; 59:4, pp. 481-488.

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 I 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).

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