# PRESS RELEASE 3 July 2009





# BioInvent and ThromboGenics Start Recruitment of Second 100 Patient Cohort in Phase II DVT Prophylaxis Study with TB-402

**Lund, Sweden and Leuven, Belgium – 3 July 2009 -** BioInvent International AB (OMXS: BINV) and ThromboGenics NV (Euronext Brussels: THR) announce that they have started recruitment of a second cohort of patients for their Phase II trial of TB-402. This follows completion of recruitment of the first cohort of 100 patients ahead of schedule. TB-402 is a novel, long acting anticoagulant that is being developed for the prevention of deep vein thrombosis (DVT) following orthopaedic surgery. The decision to move ahead with the second cohort of this trial follows unanimous advice from the external efficacy and safety monitoring board to proceed using a higher dose of TB-402.

The Phase II trial is an active (enoxaparin)-controlled, dose-escalating, multicenter, prospective, randomised, open label trial evaluating TB-402 for the prophylaxis of DVT after knee surgery. The study is assessing three different doses of TB-402 given as a single intravenous bolus injection post knee replacement surgery and will enrol a total of 300 patients across 36 centers in Europe. The objective of the study is to assess the safety and efficacy of the three escalating doses of TB-402.

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 anticoagulants. In addition, TB-402 is a long-acting agent, which means it could be given as a single dose after surgery to prevent the development of DVT. This would be an attractive option, as all current anticoagulant treatment options require daily treatment for up to several weeks.

Professor Peter Verhamme from the University of Leuven will present additional data from the earlier successful Phase I study at the XXII Congress of the International Society on Thrombosis and Haemostasis (ISTH) on 15 July, 2009, in Boston.

**Svein Mathisen, CEO of BioInvent, commented,** "We are pleased that there has been rapid progress in this study and that the efficacy and safety monitoring board unanimously recommended that we proceed to a higher dose of TB-402. It is testament to the strength of our partnership with ThromboGenics and the exciting potential of this product candidate."

Patrik De Haes, CEO of ThromboGenics, also commented, "We are very happy that this important study with TB-402 is progressing rapidly. TB-402's profile, including its novel mode of action, could allow it to address the many drawbacks associated with current anticoagulant therapy. We remain confident in the large market potential for TB-402, and believe that the current Phase II study will provide additional data to further highlight the attractive differentiating properties of this novel long-acting anticoagulant."

### **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 US alone, more than 350,000 individuals are affected by DVT or pulmonary embolism (PE) each year. Moreover, DVT and PE together may be responsible for more than 100,000 deaths in the U.S. each year.

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>2</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.

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#### Legal disclaimer

This press release contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their very nature, in the same way as research and development work in the biotech segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios described in this press release.

## **Notes to Editors:**

## 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 is currently running innovative drug projects within the areas of thrombosis, cancer and atherosclerosis. The Company has signed

<sup>&</sup>lt;sup>1</sup> 'The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism', September 15, 2008, p.1.

<sup>&</sup>lt;sup>2</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.

various strategic alliances around these product candidates and is developing them in collaboration with partners including Genentech, Roche and ThromboGenics.

These projects are based around a competitive and in substance patented antibody development platform. The scope and strength of this platform is also utilised by partners, such as ALK-Abelló, Bayer HealthCare, ImmunoGen, OrbusNeich, Sanofi-Aventis, UCB and XOMA. More information is available at <a href="https://www.bioinvent.com">www.bioinvent.com</a>.

#### **About ThromboGenics**

ThromboGenics is a biotechnology company focused on the discovery and development of innovative biopharmaceuticals 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 and as a potential therapy for stroke. ThromboGenics is also developing novel antibody therapeutics in collaboration with BioInvent International; these include TB-402 (Anti-Factor VIII), a long acting anticoagulant, 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.

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Information disclosed in this press release is provided herein pursuant to the Swedish Securities Markets Act and/or the Swedish Financial Instruments Trading Act. The information was submitted for publication at 7.30 a.m. CET, on 3 July, 2009.