



## **Positive TB-402 (Anti-Factor VIII Antibody) Phase II Data Published in *Journal of Thrombosis and Haemostasis***

**Lund, Sweden and Leuven, Belgium – 11 February 2011** – BioInvent International AB (OMXS: BINV) and co-development partner ThromboGenics NV (Euronext Brussels: THR) announce today that the positive TB-402 (Anti-Factor VIII) Phase II trial results, evaluating the product's efficacy and safety for the prevention of venous thromboembolism (VTE) after orthopaedic surgery, have been published in the *Journal of Thrombosis and Haemostasis*.

A paper entitled "Single Intravenous Administration of TB-402 for the Prophylaxis of Venous Thromboembolism after Total Knee Replacement: A Dose-Escalating, Randomised, Controlled Trial" has been published online ahead of print in *JTH*. This publication covers a recently completed dose finding Phase II trial with TB-402, with the objective of evaluating the efficacy and safety of three dose levels of single intravenous injection of TB-402 for preventing VTE after total knee surgery. The trial compared TB-402 with enoxaparin (Lovenox, sanofi-aventis), the standard treatment to prevent VTE in this setting.

The study showed that TB-402 was associated with a lower rate of VTE compared with enoxaparin. Pooled results of the TB-402 groups (0.3 mg/kg, 0.6 mg/kg and 1.2 mg/kg) showed a 22% incidence of total VTE compared with 39% for enoxaparin. In addition, TB-402 was generally well tolerated and demonstrated comparable safety to enoxaparin.

The results outlined in the article highlight that a single dose of TB-402 has the potential to improve preventive treatment of VTE after orthopaedic surgery by providing a stable, long-acting antithrombotic effect. The single dose administration may overcome poor patient compliance to therapy, one of the main causes of VTE in the real world. Furthermore, TB-402's novel mode of action could overcome the frequent monitoring and dose adjustment requirements associated with many current anticoagulant treatments.

For a full discussion of the results, please refer to the *JTH* article.<sup>1</sup> Further information is also included in the BioInvent press release dated 9 July, 2010 (see [www.bioinvent.com](http://www.bioinvent.com)).

**Professor Peter Verhamme, MD, of the University of Leuven, Belgium, and corresponding author of the *JTH* paper, said,** "We are delighted that these results with TB-402 have been published in a key academic journal. The trial data discussed in the paper demonstrate the potential benefits of TB-402 in improving treatments for the prevention of VTE after total knee surgery via a single dose. I very much look forward to the further development of TB-402 in this setting."

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<sup>1</sup> "Single Intravenous Administration of TB-402 for the prophylaxis of Venous thromboembolism after Total Knee Replacement: A Dose-Escalating, Randomised, Controlled Trial", Peter Verhamme, MD, Marco Tangelder, MD, Raymond Verhaeghe, MD, Walter Ageno, MD, Steven Glazer, MD, Martin Prins, MD, Marc Jacquemin, MD, Harry Büller, MD, *JTH*.

## **Notes to Editors:**

### **About TB-402**

TB-402 has the potential to be an 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 anticoagulation 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 simple approach to prophylaxis would be an attractive option, as all current anticoagulant treatment options require daily treatment for up to several weeks.

### **About Venous Thromboembolism (VTE)**

VTE is the third most common cardiovascular disease after myocardial infarction and stroke.<sup>2</sup> It includes both deep vein thrombosis (DVT) and pulmonary embolism (PE). DVT is caused when a blood clot forms in a deep vein, most commonly in the deep veins of the lower leg. PE occurs when a blood clot blocks the main artery of the lung or one of its branches. DVT and PE are major public health issues. It is estimated that in the US alone, more than 600,000 patients are treated for venous thromboembolisms such as DVT or PE each year.<sup>3</sup> Moreover, DVT and PE together may be responsible for more than 100,000 deaths in the US each year.<sup>4</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 US if current trends persist.<sup>5</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. 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, vascular disease and cancer. The Company's lead product ocriplasmin (microplasmin) has completed two Phase III clinical trials for the pharmacological treatment of symptomatic vitreomacular adhesion (sVMA). Ocriplasmin 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 Euronext Brussels under the symbol THR. More information is available at [www.thrombogenics.com](http://www.thrombogenics.com).

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<sup>2</sup> "The role of oral direct thrombin inhibitors in the prophylaxis of venous thromboembolism", Hawkins D, Pharmacotherapy, October 24, 2004; 10 Pt 2, pp.179S-183S.

<sup>3</sup> Barclays Capital Equity Research Report on New Anticoagulants, August 5, 2009

<sup>4</sup> "The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism," September 15, 2008, p.1.

<sup>5</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.

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