

ThromboGenics and BioInvent Have Dosed the First Patient in Phase IIb Trial of TB-402 (Anti-Factor VIII) for Venous Thromboembolism (VTE) Prophylaxis

Trial to assess the benefits of partial Factor VIII inhibition in total hip replacement surgery patients

Leuven, Belgium and Lund, Sweden – 27 April 2011 – ThromboGenics NV (Euronext Brussels: THR) and co-development partner BioInvent International (OMXS: BINV) announce today that the first patient has been dosed in a Phase IIb trial with their novel long-acting anticoagulant TB-402 (Anti-Factor VIII) for the prophylaxis of venous thromboembolism (VTE) after total hip surgery.

The Phase IIb study is a multicenter, double blind, randomised controlled trial. It is comparing the safety and efficacy of two dose levels of TB-402, given as a single intravenous infusion after hip surgery, with the recently approved Factor Xa inhibitor rivaroxaban. The trial will enrol 600 patients across 41 centers in Europe. Results are expected in the second half of 2012.

TB-402 is a recombinant human monoclonal antibody that has a novel mode of action. It targets Factor VIII, a key component of the coagulation cascade. An important benefit of TB-402 is that a single injection could provide a stable, long-acting antithrombotic effect, for the prophylaxis of VTE after orthopaedic surgery, which is expected to lead to reduced nursing time and improved patient compliance.

Importantly, TB-402's anti-coagulant activity is easily reversible using Factor VIII, in case of bleeding or need for surgery. In contrast, certain newer anticoagulant therapies lack an antidote which can make it difficult to manage serious bleeds or which may complicate or delay acute surgical procedures.

In 2010, TB-402 reported positive results in a 315-patient Phase IIa trial for VTE prophylaxis after knee replacement surgery, compared with enoxaparin, the standard treatment for preventing VTE in this setting. The positive pooled results of three doses of TB-402 (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 ($p < 0.05$). In addition, TB-402 was generally well tolerated and demonstrated comparable safety to enoxaparin. The results were published in the *Journal of Thrombosis and Haemostasis* in February 2011¹.

Dr. Patrik De Haes, CEO of ThromboGenics, commenting on the announcement said: "TB-402 has already shown the potential to significantly improve the treatment of VTE in the post-surgery setting. We hope that this study will confirm these promising results and give us a better understanding of the overall benefits that TB-402 can provide to this patient group. We believe that VTE prophylaxis with a single dose of TB-402 that lasts for several weeks is

¹"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*.

a simple and attractive option for physicians and patients when compared with other anticoagulant regimes that are currently available.”

Svein Mathisen, CEO of BioInvent, added: “We are delighted about the product’s demonstrated success in earlier trials and believe that it represents an innovative approach to the prevention of VTE after hip orthopaedic surgery. TB-402 promises to become a very important entrant into the anticoagulant market where the product would fill a significant unmet need.”

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About TB-402

TB-402 has the potential to be an important new entrant into the anticoagulant market. TB-402 is a long-acting agent, which means it could be given as a single dose to prevent the development of VTE 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. Importantly, this could lead to better patient compliance. 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, as well as the need for anticoagulation monitoring. These are the two main drawbacks associated with current anticoagulant therapy.

About Venous Thromboembolism (VTE)

VTE is the third most common cardiovascular disease after myocardial infarction and stroke.² 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.³ Moreover, DVT and PE together may be responsible for more than 100,000 deaths in the US each year.⁴

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.⁵ 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.

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

³ Barclays Capital Equity Research Report on New Anticoagulants, August 5, 2009

⁴ “The Surgeon General’s Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism,” September 15, 2008, p.1.

⁵ “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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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. ThromboGenics is also developing novel antibody therapeutics in collaboration with BioInvent International; these include TB-402 (anti-Factor VIII), a long-acting anticoagulant in Phase II, and TB-403 (anti-PlGF) in Phase Ib/II for cancer in partnership with Roche.

ThromboGenics is headquartered in Leuven, Belgium. The Company is listed on NYSE Euronext Brussels under the symbol THR. More information is available at www.thrombogenics.com.



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.

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.