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# BioInvent and ThromboGenics report positive Phase I results for anti-PIGF cancer therapeutic TB-403

# Approval also received to start second repeat-dose Phase I study in patients with advanced cancer

**Lund, Sweden and Leuven, Belgium – 3 June 2008** - BioInvent International AB (OMX Nordic Exchange Stockholm: BINV) and co-development partner ThromboGenics NV (Euronext Brussels: THR) today reported that the results from the first Phase I study of novel anti-cancer agent TB-403 showed that it is safe and well tolerated, with pharmacokinetic properties enabling it to be developed for the treatment of cancer. The companies also announced that they have received approval from the regulatory authorities in Denmark to initiate a second repeat-dose Phase I clinical trial of TB-403 in patients with advanced solid tumours.

TB-403 is a monoclonal antibody that targets the angiogenic factor PIGF (placental growth factor). The product has demonstrated inhibition of PIGF-associated angiogenesis and tumour growth in animal models, without affecting healthy tissues. The completed Phase I study was a double-blind, randomised trial testing a single-dose of TB-403 at three escalating levels or placebo in 16 healthy male subjects. The results of the trial have shown that TB-403 met both primary endpoints regarding safety and tolerability, and secondary endpoints examining pharmacokinetics. These results have provided the basis for a safe and efficient introduction of the compound into a subsequent repeat-dose trial in patients for which BioInvent and ThromboGenics have now received approval.

The second Phase I trial will be a study of tolerability, pharmacokinetics and pharmacodynamics in patients with advanced cancer. Up to 30 patients with metastatic or unresectable solid tumours will be enrolled in this open, dose escalation multi-dose study. The study will take place in Denmark and patient recruitment is due to begin shortly.

**Svein Mathisen, CEO of BioInvent, commenting on today's announcement, said:** "We are pleased at the continued progress seen in our collaboration with ThromboGenics and at the success of this product in Phase I. Based on these data, we look forward to embarking imminently on the planned second Phase I study in patients with advanced cancer, while we continue to prepare for future development and commercialisation."

Professor Désiré Collen, CEO and Chairman of ThromboGenics, added: "This is an important milestone for ThromboGenics and our partner BioInvent. This study reinforces our belief that TB-403 has the potential to become a significant treatment for cancer due to TB-403's unique mode of action. TB-403 blocks the formation of new blood vessels in the cancer tumour without affecting healthy tissues. We are delighted that the vision we shared with BioInvent is progressing and with today's news, is becoming more tangible."

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

#### **About TB-403**

Angiogenesis inhibitors such as TB-403 are therapeutic agents that work by blocking the development of new blood vessels, thereby depriving growing cancer tumour cells of oxygen and nutrients. This approach in turn is thought to stop the tumour from growing and spreading to other parts of the body. Currently available angiogenesis inhibitors specifically target vascular endothelial growth factor (VEGF), which plays an important role in promoting the formation of blood vessels. PIGF is a homologue of VEGF but, unlike VEGF, it does not affect normal, physiological angiogenesis and is only involved in the angiogenesis in the diseased tissue. Therefore, as an inhibitor of PIGF, TB-403 is likely to inhibit tumour growth without the side effects associated with other anti-angiogenic therapies.

ThromboGenics and BioInvent also intend to develop TB-403 for eye diseases, to block uncontrolled blood vessel growth in conditions such as age-related macular degeneration (AMD) and diabetic retinopathy.

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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:

**BioInvent International AB**, listed on the OMX Nordic Exchange 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, atherosclerosis and ophthalmic diseases. In January 2007 the Company announced a major strategic alliance with American-based Genentech, Inc. in the cardiovascular field.

These projects are based on a competitive and in substance patented technology 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.

The Company, which currently has 95 employees, is located at Ideon in Lund.

**ThromboGenics NV** is a biotechnology company focused on discovery and development of biopharmaceuticals for the treatment of a range of vascular diseases. The Company has several programs in Phase II clinical development including microplasmin, which is being evaluated as a treatment for vitreoretinal disorders and as a thrombolytic agent for vascular occlusive diseases, including acute stroke. ThromboGenics is also developing novel antibody therapeutics in collaboration with BioInvent International; these include TB-402 (Anti-Factor VIII), scheduled to enter Phase II clinical development in 2008, and TB-403 (Anti-PIGF), which is scheduled to enter a Phase Ib clinical trial in mid-2008 for the treatment of 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 and has subsidiaries in Dublin, Ireland and New York, U.S. The Company is listed on Eurolist by Euronext Brussels under the symbol THR. More information is available at <a href="https://www.thrombogenics.com">www.thrombogenics.com</a>.

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