PRESS RELEASE
19 March 2015

# BioInvent confirms clinical strategy for BI-505 and plans to conduct phase IIa trial in multiple myeloma post-stem cell transplant patients in the US

*The ability of BI-505 to prevent or delay relapse of multiple myeloma (MM) to be investigated in clinical study conducted by leading clinicians at University of Pennsylvania*

**Lund, Sweden – 19 March, 2015** – BioInvent International AB (OMXS: BINV) completed a strategic analysis of its ICAM-1 targeted phase II antibody BI-505 with thought leaders to garner support on the development of BI-505.

Based on the analysis of BI-505's data, a clear direction emerged that BI-505 is uniquely positioned to increase the potential depth and quality of response in patients receiving standard of care treatment for multiple myeloma. Many MM patients initially achieve a good response from existing therapy; however, patients can eventually relapse and succumb to the cancer as a consequence of myeloma cells that remain in the patient after treatment (minimal residual disease).

BioInvent intends to conduct a Phase IIa study in MM patients that have undergone autologous stem cell transplantation (ASCT) to investigate the ability of BI-505 to increase the depth and quality of response after ASCT in combination with standard of care. Results from the open-label trial will be compared to a historical data from a matched cohort of patients. The intention is to recruit approximately 30 patients, and study start is planned for early 2016. The study will be conducted as an investigator sponsored study in close collaboration with leading clinicians at the Abramson Cancer Center of the, University of Pennsylvania.

"There is a great need within the multiple myeloma patient population for targeted treatment options which could deepen the responses that can be achieved with currently available treatments. BI-505 has a unique mechanism of action which could target residual disease that eventually leads to relapse in this population, and the planed study will address this hypothesis"**, said Brendan Weiss MD an Assistant Professor of Medicine at the University of Pennsylvania in Philadelphia.**

"BI-505 may be uniquely positioned to prevent or delay relapse of multiple myeloma. This patient need is currently not addressed effectively by other treatment options and relapse eventually occurs in patients. We are delighted with the opportunity to conduct a clinical study with the University of Pennsylvania prior to progressing to a larger clinical trial"**, stated Michael Oredsson, President and CEO of BioInvent.**

As a consequence of this strategic analysis of the potential of BI-505 in MM patients post ASCT, BioInvent will conclude the its smouldering myeloma study. Smouldering myeloma does not constitute a relevant commercial development opportunity for BioInvent, and the mechanism of action of BI-505 is not believed to be as relevant in this indication.

**To the editors:**

**About BioInvent**
BioInvent International AB is a research-based pharmaceutical company focused on the discovery and development of innovative antibody-based drugs against cancer.

The company has unique expertise in antibody drug development from initial concept to late clinical phase. The screening tool, F.I.R.S.T.™, and the antibody library, n-CoDeR®, are two patented tools that enable identification of relevant human antibodies and disease targets during the discovery phase. BioInvent has also considerable experience in and a facility for process development and production of antibodies for clinical studies. The scope and strength of this platform is also used to develop antibody-based drugs in collaboration with partners who finance the development of the new drug, and provide BioInvent with the right to milestone payments and royalties on sales. These partners include Bayer Pharma, Daiichi Sankyo, Mitsubishi Tanabe Pharma, Servier and Xoma. More information is available at www.bioinvent.com.

**About BI-505, MM and MRD**
Minimal residual disease (MRD) status is increasingly considered to be the most important predictor of multiple myeloma relapse. Preclinical data with BI-505 indicates that its macrophage-mediated mechanism is effective at killing the small numbers of myeloma cells that will cause relapse. In addition, myeloma cells are critically dependent on adhesive interactions with stromal cells for survival and for development of drug-resistance. Thus, BI-505 targeting of ICAM-1 could help overcome MRD by concerted mechanisms. The previously shown favourable clinical safety profile of BI-505 also makes it suitable for treatment of this patient population.

The unmet medical need in patients with residual disease is high and available MM drugs may be unsuitable either due to toxicity or low beneficial effects, often both. It is believed that current and new drugs in clinical development for MM will not adequately address this need in the treatment of MM patients.

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