



## **Multiple myeloma phase II study of BioInvent's antibody BI-505 ready to start**

**Lund, Sweden – 18 April 2016** – BioInvent International (BINV) announced today that patient recruitment into the trial can now start in the upcoming clinical Phase II study with the antibody BI-505 in patients with multiple myeloma, as necessary regulatory approvals have been obtained. The first patient is expected to be dosed in May.

Multiple myeloma is a bone marrow cancer which affects more than 120,000 people globally every year<sup>1</sup>. Initial treatment is often successful, but unfortunately, most patients will relapse and in 2015, nearly 90,000 patients died as a result of the disease<sup>2</sup>. BI-505 is a novel immuno-oncology treatment with the potential to prevent or delay relapse of multiple myeloma.

"The start of this Phase II study is an important milestone in the development of BI-505, an antibody with the potential to offer multiple myeloma patients a longer and healthier life," **says Anna Wickenberg, Vice President of Clinical Development at BioInvent.**

The clinical study will be conducted by BioInvent in collaboration with investigators at the University of Pennsylvania in the United States. It aims to document the ability of BI-505 to deepen the therapeutic response and thereby prevent or delay relapse of multiple myeloma in patients undergoing autologous stem cell transplantation (ASCT) with high-dose melphalan as part of their standard of care. The study will enroll approximately 90 patients undergoing ASCT whereof half will receive BI-505 as an add-on treatment to their standard of care.

The study is open-label, randomized, and includes a control group receiving only standard treatment. The open-label design will allow for patient outcomes to be monitored on an individual basis throughout the study. The primary efficacy evaluation of BI-505 will be made after 100 days with the primary endpoint being the proportion of patients in stringent complete response (sCR). Patients will thereafter be followed over three years to document progression-free survival (PFS). As a secondary endpoint, patients will also be monitored for any residual, disease known as "Minimal Residual Disease" (MRD), to assess deep responses.

### **To the editors:**

#### **About BI-505**

BI-505 is a human antibody against ICAM-1 developed by BioInvent which will be clinically tested in cooperation with researchers at University of Pennsylvania as an immuno-oncological therapy to prevent or delay relapse in patients with multiple myeloma (a form of bone marrow cancer) undergoing stem-cell transplantation. Preclinical data indicates improved activity against myeloma when BI-505 is administered in combination with Velcade® or Revlimid®. BI-505's favourable safety profile has been demonstrated in a previous phase I trial. This and the unique mechanism of action, "flagging" remaining myeloma cells for elimination by actively recruited macrophages, as well as the potential to inhibit ICAM-1 dependent survival signals between myeloma cells and tumour stroma, indicate a unique possibility of improving the therapeutic effect of stem-cell transplantation and other cancer therapies.

**About BioInvent**

BioInvent International AB develops immune oncology drugs. With one of the world's largest antibody libraries, and a unique, proprietary discovery method, BioInvent can identify the optimal cellular targets and antibodies for the treatment of various tumor types. BioInvent has also considerable experience in, and a facility for, process development and production of antibodies for clinical studies. This makes it possible to develop proprietary drug projects and also to supply leading international pharmaceutical companies with effective tools for their drug development. BioInvent currently has three proprietary projects in or close to clinical development and partnership agreements with seven global pharmaceutical and biotech companies. More information is available at [www.bioinvent.com](http://www.bioinvent.com).

**For further information, please contact:**

Michael Oredsson  
President and CEO  
+46 (0)46 286 85 67  
+46 (0)70716 89 30  
[michael.oredsson@bioinvent.com](mailto:michael.oredsson@bioinvent.com)

**BioInvent International AB (publ)**

Co. reg. No: 556537-7263  
Visiting address: Sölvegatan 41  
Mailing address: 223 70 LUND  
Phone: +46(0)46 286 85 50  
[info@bioinvent.com](mailto:info@bioinvent.com)  
[www.bioinvent.com](http://www.bioinvent.com)

**References:**

1. GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of New Cancers in 2015.
2. GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of Cancer Deaths in 2015.

*The 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.*