



## **BioInvent Announces Approval to start Phase I Trial for BI-505 in Multiple Myeloma**

**Lund, Sweden – 11 August 2009** - BioInvent International AB (OMXS: BINV) today announces that it has received clearance from the U.S. Food & Drug Administration (FDA) to initiate a Phase I open dose-escalation study with its therapeutic cancer antibody BI-505 in patients with advanced Multiple Myeloma.

The Phase I study will investigate safety, pharmacokinetics, pharmacodynamics, and will aim to define the optimal biological dose of the antibody for phase 2 drug development. BioInvent will recruit approximately 40 patients with advanced Multiple Myeloma across 3 centres (possibly extending to 4) in the U.S. as part of the study.

BI-505 is a fully human antibody derived from BioInvent's proprietary n-CoDeR<sup>®</sup> library and targets the adhesion molecular ICAM-1 leading to cell death. ICAM-1 is highly expressed in several tumours but is not widely expressed in normal tissue. Preclinical results have demonstrated that the compound is more efficacious to fight tumours than existing drugs. BI-505 has been granted orphan drug designation in the U.S. and Europe for the indication of Multiple Myeloma.

**Svein Mathisen, CEO of BioInvent, commented,** "We are delighted that the FDA accepted our first IND, an important step in the development of the company as we further increase our presence in the U.S. BI-505 is our fourth product in clinical development. We believe that it has application in multiple myeloma patients resistant to other therapies, as in many cases expression of ICAM-1 in tumour cells is known to be up-regulated. This, together with strong pre-clinical results compared to the current marketed drug for the indication, suggests that BI-505 could address major unmet medical need, both in multiple myeloma and potentially other indications"

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### **About BI-505**

The drug candidate BI-505 is a fully human antibody that targets the adhesion protein ICAM-1 (also called CD54). In tumour cells the expression of ICAM-1 is elevated, making it an attractive target for a therapeutic antibody. Targeting ICAM-1 with an antibody leads to cell death in the target tumour cells, a characteristic that had not previously been recognised, and hence representing a novel approach to targeting tumours through ICAM-1. In addition to inducing cell death through direct cell cytotoxicity (apoptosis), the antibody also stimulates the immune system to eliminate tumour cells (including through antibody dependent cell-mediated cytotoxicity, ADCC). BI-505 has been shown to be more effective at killing tumours than existing drugs in several animal models. Prior to BioInvent's screen and preclinical studies, the ability of anti-ICAM-1 to apoptosis had not been recognized.

### **For further information, please contact:**

#### ***BioInvent International AB***

Svein Mathisen  
President & CEO  
Tel: +46 (0)46-286 85 67  
Mobile: +46 (0)708-97 82 13  
E-mail: [svein.mathisen@bioinvent.com](mailto:svein.mathisen@bioinvent.com)

Cristina Glad  
Executive Vice President  
Tel: +46 (0)46-286 85 51  
Mobile: +46 (0)708-16 85 70  
E-mail: [cristina.glad@bioinvent.com](mailto:cristina.glad@bioinvent.com)

College Hill (media enquiries)  
Holly Griffiths, Sue Charles and John Mc Intyre  
Tel: +44 (0)20 7457 2020  
Erik Clausen, Kena Hudson (US)  
Tel: +1 415-230-5385  
E-mail: [bioinvent@collegehill.com](mailto:bioinvent@collegehill.com)

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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:**

**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 is currently running innovative drug projects within the areas of thrombosis, cancer and atherosclerosis. The Company has signed various strategic alliances around these product candidates and is developing them in collaboration with partners including Genentech, Roche and ThromboGenics.

These projects are based around a competitive and in substance patented antibody development 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. More information is available at [www.bioinvent.com](http://www.bioinvent.com).

**BioInvent International AB (publ)**

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

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