

PRESS RELEASE  
24 January 2013



## **Positive results from the BI-505 phase I study in multiple myeloma**

**Lund, Sweden – January 24, 2013** – BioInvent International (OMXS:BINV) announced today the first results from the BI-505 phase I study in patients with multiple myeloma. The study has reached a final stage and the preliminary analysis shows that BI-505 has an advantageous safety profile. In cohorts where extended therapy was available, 24 % of the patients had stable disease for at least two months, indicating effect of BI-505. The final conclusions of the study will be available at a later time-point. The optimal dose has been defined according to the study protocol and will be used in the next clinical trial which is approved by the health authorities.

Cristina Glad, CEO of BioInvent, commented: "We are delighted that this phase I trial has shown that BI-505 has an advantageous safety profile and that stable disease is observed in a significant number of patients. Although this is still early stage data, the results are encouraging and add to our excitement about the potential of this therapy to significantly improve the treatment of patients with multiple myeloma. We look forward to progress with BI-505 into further development."

"These results are of significant clinical interest. I am very encouraged by the safety profile of BI-505 and by the fact that in this heavily pretreated population, we were noticing patients with stable disease for quite some time." said the Coordinating Investigator of the BI-505 study, Guido Tricot, M.D., at the University of Iowa in Iowa City. "We look forward to further clinical trials with this antibody to determine its full potential, with the goal of ultimately improving outcomes for myeloma patients."

BI-505 is a human antibody selected from the n-CoDeR<sup>®</sup>-library and fully owned by BioInvent. It is directed against the ICAM-1 adhesion protein, which is highly expressed on multiple myeloma cells. BI-505 has demonstrated significant anti-tumor activity in several relevant models of multiple myeloma.

Thirty-five patients with relapsed or refractory disease after at least two previous regimens with other drugs are included in the phase I, dose escalation study. The primary objective is to determine the safety and tolerability of BI-505 in patients with advanced disease. Pharmacokinetics and pharmacodynamic variables including relevant biomarkers for tumor response are also being evaluated in order to determine the optimal dose for further clinical development. The study is being conducted at seven sites in the US and Europe.

Groups of patients are treated with increasing doses of BI-505 (0,0004 – 20 mg/kg; eleven dose levels) every second week over a four-week period, with a possibility of extended therapy every two weeks until disease progression for patients at dose level six and onwards.

The preliminary assessment demonstrates that BI-505 has a favorable safety profile with a low number of reported adverse events. Temporary infusion-related reactions were observed when the first dose was given which is commonly seen. Despite advanced disease, 7 of the 29 patients on extended therapy (at dose level six and onwards) had stable disease for at least two months. A dosing regimen of 10 mg/kg every second week resulted in complete saturation of the ICAM-1 epitopes on the patient's bone marrow myeloma cells. The 10 mg/kg dose will thus be used in the next clinical trial which has already been approved by the health authorities.

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**To the 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's pipeline currently includes three product candidates for the treatment of cancer. 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 and ThromboGenics.

The company's competitive position is underpinned by n-CoDeR®, a proprietary antibody development platform. The scope and strength of this platform is also utilised by partners, such as Bayer HealthCare, Daiichi Sankyo, Mitsubishi Tanabe and Servier. More information is available at [www.bioinvent.com](http://www.bioinvent.com).

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