



## **BioInvent receives FDA orphan designation for BI-1206 for mantle cell lymphoma**

- *BioInvent is currently investigating this combination in Phase I/IIa study*
- *Significant unmet medical need in mantle cell lymphoma*

**Lund, Sweden – January 30, 2019** – BioInvent International AB (OMXS: BINV) announces today that the U.S. Food and Drug Administration (FDA) has granted the Company orphan designation for its proprietary antibody BI-1206 for the treatment of mantle cell lymphoma (MCL).

Orphan designation is intended to support companies developing treatments that target rare medical conditions and are expected to provide significant therapeutic advantage over existing medicines. The orphan designation from the FDA provides certain incentives to BioInvent, including a 7-year market exclusivity in the U.S once a New Drug Application (NDA) or Biologics License Application (BLA) has been approved, and also availability of grants exclusively for orphan drug products.

BioInvent is currently conducting a dose escalation, consecutive-cohort, open-label Phase I/IIa study of BI-1206 with approximately 30 patients across sites in the EU and the U.S. The trial evaluates BI-1206 in combination with rituximab in patients with indolent relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL). MCL is one of the targeted sub-indications, along with follicular lymphoma (FL) and marginal zone lymphoma (MZL).

"This orphan designation for BI-1206 is very good news for BioInvent, and most importantly for patients suffering from this very serious condition. There is a significant unmet medical need, as there are presently few treatment options for patients suffering from mantle cell lymphoma. We are looking forward to generating data from our Phase I/IIa trial to support the use of BI-1206 in combination with rituximab in this indication," says Martin Welschof, CEO of BioInvent.

### **About BioInvent**

BioInvent International AB (OMXS: BINV) is focused on the discovery and development of novel and first-in-class immuno-modulatory antibodies to treat cancer. The Company's lead program is BI-1206, currently in Phase I/II for non-Hodgkin lymphoma and chronic lymphatic leukemia. BioInvent's pre-clinical portfolio is focused on targeting key immune suppressive cells and pathways of the tumor microenvironment, including regulatory T cells, tumor-associated myeloid cells and mechanisms of antibody drug-resistance. The Company has a strategic research collaboration with Pfizer Inc., and partnerships with Transgene, Bayer Pharma, Daiichi Sankyo, and Mitsubishi Tanabe Pharma. BioInvent generates near term revenues from its fully integrated manufacturing unit producing antibodies for third parties for research through to late-stage clinical trials. More information is available at [www.bioinvent.com](http://www.bioinvent.com).

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

Martin Welschof, CEO  
+46 (0)46 286 85 50  
[martin.welschof@bioinvent.com](mailto:martin.welschof@bioinvent.com)

Hans Herklots, LifeSci Advisors  
+41 79 598 71 49  
[hherklots@lifesciadvisors.com](mailto:hherklots@lifesciadvisors.com)

### **BioInvent International AB (publ)**

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

*The press release contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as 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.*

*This information is information that BioInvent International AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 8.40 a.m. CET, on January 30, 2019.*

