PRESS RELEASE
7 January, 2016

BioInvent announces FDA acceptance of the Investigational New Drug application for the phase I/IIa study with TB-403

Lund, Sweden – 7 January 2016 – BioInvent International (OMXS: BINV) today announces that the FDA has completed the safety review of its Investigational New Drug (IND) application and have concluded that the proposed pediatric clinical investigation can proceed. The IND application is for a Phase I/IIa study that will evaluate the efficacy and safety of TB-403 for the treatment of relapsed or refractory medulloblastoma. This is a rare, life-threatening brain tumor that mainly affects children.

The study, which is planned to commence in Q1 2016, will be conducted at a number of specialist centers in the United States. Initial results from the study are expected by early 2017.

TB-403 is a humanized monoclonal antibody against placental growth factor (PlGF) which is expressed in several types of cancer, including medulloblastoma. High expression of the PlGF receptor neuropilin 1 has been shown to correlate with poor overall survival. Treatment with TB-403 in pre-clinical models for medulloblastoma has demonstrated beneficial effects on tumor growth and survival. The antibody can potentially be used in other pediatric cancer indications, including neuroblastoma, Ewing sarcoma or alveolar rhabdomysarcoma.

A favourable safety profile of TB-403 has been demonstrated in previous clinical trials in healthy volunteers and adult patients with various types of solid tumors.

“We are delighted that the FDA has accepted our IND for TB-403. This is a milestone for commencing the phase I/IIa study evaluating TB-403 in rare pediatric brain cancers according to plans communicated in December 2015. The study will be conducted at an attractive cost and efficacy signals in patients will provide opportunities to approach the FDA regarding expedited approval. TB-403 may in this scenario get a rapid pathway to launch,” **says Michael Oredsson, CEO of BioInvent.**

The TB-403 drug project is conducted in cooperation with Oncurious, a subsidiary of the Belgian biopharma company ThromboGenics. BioInvent is paying half of the development costs and has the right to 40 percent of all future revenue from the project.

To the editors:

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, but 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.

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

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
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.

Information disclosed in this press release is provided herein pursuant to the Swedish Financial Instruments Trading Act. The information was submitted for publication at 12.30 a.m. CET, on 7 January, 2016.