

## **ONCURIOUS NV Announces European Commission Confirmed Orphan Medicinal Product Designation for TB-403 for Medulloblastoma**

**Leuven, Belgium 17 January 2017**, – ONCURIOUS NV, an emerging oncology company focused on the development of innovative orphan drugs for the treatment of pediatric tumors, today announces that the European Commission has confirmed the orphan drug designation for TB-403 for medulloblastoma. Today's decision by the EC follows the earlier positive opinion issued by the European Medicine Agency (EMA).

TB-403 is a humanized monoclonal antibody against placental growth factor (PlGF). PlGF is expressed in several types of cancer, including medulloblastoma. In medulloblastoma patients, high expression of the PlGF receptor neuropilin 1 has been shown to correlate with poor overall patient survival.

An orphan drug designation is for “medicines to be developed for the diagnosis, prevention or treatment of rare diseases that are life-threatening or very serious”.

Today's confirmation by the EC follows an earlier in-depth review and positive opinion on the drug candidate by the EMA Committee for Orphan Medicinal Products (COMP). The COMP gathers a group of experts chosen on the strength of their qualifications and a number of patient organization representatives. Altogether, the COMP assesses the potential incremental benefits of a drug candidate versus existing treatments.

TB-403 is currently being evaluated in a Phase I/IIa clinical trial for treatment of medulloblastoma, a rare, life-threatening pediatric cancer.

The clinical trial is being conducted in partnership with the Neuroblastoma and Medulloblastoma Translational Research Consortium (NMTRC). The Consortium is a collaboration of 25 US academic medical centers, teaching hospitals and other entities, with the purpose of facilitating and conducting collaborative research activities and investigations of new treatments for neuroblastoma, medulloblastoma and other pediatric cancers. NMTRC is headquartered in Grand Rapids, MI, USA.

ONCURIOUS nv is working with BioInvent International AB as a development partner for this project.

### **Patrik De Haes, MD, Executive Chairman of ONCURIOUS nv comments**

*“We are very happy with today's news. Gaining this orphan-drug designation is an important validation of the TB-403's scientific rationale and preclinical data. It also offers very valuable potential benefits including protocol assistance and fee waivers, as well as 10-year market exclusivity once the medicine is on the market in Europe.”*

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#### **About ONCURIOUS NV**

ONCURIOUS NV is an oncology company focused on the development of innovative medicines for the treatment of pediatric cancers. Oncurious is a venture between ThromboGenics NV and VIB, a leading life science research institute in Flanders, Belgium.

Oncurious is currently recruiting patients in a Phase I/IIa clinical program with TB-403 for the treatment of medulloblastoma, a rare life-threatening brain tumor that mainly affects children.

More information on Oncurious NV can be found at [www.oncurious.com](http://www.oncurious.com)

#### **About the NMTRC**

The Neuroblastoma and Medulloblastoma Translational Research Consortium (NMTRC) is a group of 25 universities and children's hospitals headquartered at the Helen Devos Children's Hospital, Grand Rapids, MI, USA that offer a nationwide network of childhood cancer clinical trials. These trials are based on the research from a group of closely collaborating investigators who are linked with laboratory programs developing novel therapies for high-risk neuroblastoma and medulloblastoma.

More information on NMTRC can be found at: <http://nmtrc.org/>

#### **About BioInvent**

BioInvent International AB (OMXS:BINV) is focused on the discovery and development of novel and first-in-class immuno-regulatory antibodies to treat cancer. The Company's clinical programmes are BI-1206, currently in a Phase I/II for non-Hodgkin's lymphoma and chronic lymphatic leukaemia and TB-403, in cooperation with Oncurious, currently in Phase I/II for medulloblastoma. BioInvent has an exciting pre-clinical portfolio based on novel immuno-modulatory antibodies that target regulatory T cells (T-regs) and tumour-associated myeloid cells. In December 2016, the Company signed a strategic research collaboration with Pfizer Inc. BioInvent also works with leading academic institutions including the University of Southampton, Cancer Research UK, and Penn Medicine. BioInvent generates revenues from global partnerships, including Bayer Pharma, Daiichi Sankyo, and Mitsubishi Tanabe Pharma and from its manufacturing facility for the production of antibodies for research through to late-stage clinical trials. More information is available at [www.bioinvent.com](http://www.bioinvent.com).

#### **Important information about forward-looking statements**

*Certain statements in this press release may be considered "forward-looking". Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason. Additional information concerning risks and uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the Company's Annual Report.*

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