

PRESS RELEASE  
2 May 2016



## **BioInvent, Oncurios NV and NMTRC initiating Phase I/IIa study with TB-403 for the treatment of Medulloblastoma**

**Lund, Sweden – 2 May 2016** – BioInvent International (BINV) today announce it has initiated a Phase I/IIa study that will evaluate the safety and tolerability, and explore the preliminary efficacy, of TB-403 for the treatment of relapsed or refractory medulloblastoma, a rare, life-threatening brain tumor that mainly affects children.

Today's study initiation follows the earlier announced partnership between BioInvent, its TB-403 project partner Oncurios, and the Neuroblastoma and Medulloblastoma Translational Research Consortium (NMTRC) in the US. NMTRC 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.

Headquartered at the Helen DeVos Children's Hospital in Grand Rapids, MI, USA, NMTRC is the key clinical trial partner for this Phase I/IIa study. The study aims at recruiting a minimum of 27 patients, with first results expected to be reported in 2017.

TB-403 is a humanized monoclonal antibody against placental growth factor (PIGF) which is expressed in several types of cancer, including medulloblastoma. A paper in *Cell* in February 2013 (*Cell*, 152, 1065-76, 2013), highlighted for the first time that PIGF plays a role in the growth and spread of medulloblastoma. The paper was based on pre-clinical research conducted by Prof Rakesh Jain from the Massachusetts General Hospital at Harvard Medical School (Boston) and the team of Prof Peter Carmeliet from Vesalius Research Center, VIB Katholieke Universiteit, Leuven, Belgium.

Treatment with TB-403 in pre-clinical models for medulloblastoma has demonstrated beneficial effects on tumor growth and survival. TB-403 has been shown to have a favorable safety profile in previous clinical trials in healthy volunteers and adult patients with various types of solid tumors.

The drug candidate TB-403 is jointly owned by BioInvent and the Belgian biopharma company Oncurios NV.

**Michael Oredsson, CEO of BioInvent commented,** "The initiation of this study is a key step in the development of this new targeted potential treatment for children with devastating brain cancers. We are looking forward to be working with NMTRC's experienced investigator network to complete this study in a timely manner."

**Dr Patrik De Haes, Executive Chairman of Oncurios, commented,** "We are pleased to announce the initiation of this important Phase I/IIa study with TB-403, a key corporate milestone for Oncurios. Given the encouraging pre-clinical data generated with TB-403 in Leuven and Boston, we are hopeful that this novel antibody, targeting placental growth factor, will provide an improved treatment option for children afflicted with this lethal brain tumor."

**Giselle Sholler, MD MSC, of NMTRC, commented,** "We are delighted to be starting this study, which is very much in line with our mission to bring forward new therapies that could improve the quality of life and survival of children with medulloblastoma. We believe that with its unique mode of

action TB-403 could offer an important solution to address this tremendous unmet medical need.”

**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 and 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](http://www.bioinvent.com).

**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 and VIB, a leading life science research institute in Flanders, Belgium.

Oncurious plans to initiate a Phase I/IIa clinical program with TB-403 for the treatment of medulloblastoma, a rare, life-threatening brain tumor that mainly affects children. Final preparations to enable opening the study for enrollment are ongoing. BioInvent International is a co-development partner for the planned Phase I/IIa TB-403 clinical trial. 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.

NMTRC's mission is to create a national collaborative effort of researchers, oncologists and family advocates to bring forward new therapies for children with relapsed neuroblastoma and medulloblastoma with the goal of improving the quality of life and survival of children with neuroblastoma and medulloblastoma. More information on NMTRC can be found at: <http://nmtrc.org/>.

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