



PRESS RELEASE

Oncurious NV Reports Encouraging Data from Phase 1 Dose Escalation Study of TB-403 in Paediatric Subjects with Relapsed or Refractory Medulloblastoma Presented at the American Association for Cancer Research 2021 Annual Meeting

Leuven, Belgium, Boston, MA, US, 12 April 2021 – 7.30 AM CET – ONCURIOUS NV, a Belgium-based biotech company focused on developing innovative oncology treatments, today announces that encouraging data from a Phase 1 dose escalation study of TB-403 in pediatric subjects with relapsed or refractory medulloblastoma (MB), was presented at the annual meeting of the American Association for Cancer Research (AACR).

The data was presented by Dr. Giselle Sholler, Director, Isabella Santos Foundation Solid and Rare Tumor Program, Chair at Beat Childhood Cancer Research Consortium, and Professor, Paediatric Oncology at the Levine Children's Hospital in Charlotte, NC.

The Phase 1 trial (ONC-403-001) was an open-label, multi-center, dose escalation study of TB-403 in a total of 15 pediatric subjects - 11 with relapsed or refractory MB, 2 with Ewing Sarcoma (ES) and 2 with alveolar rhabdomyosarcoma (ARMS). The study was conducted in conjunction with the Beat Childhood Cancer Research Consortium, Massachusetts General Hospital and Atrium Health Levine Children's Hospital.

The study evaluated 4 dose levels of TB-403: 20 mg/kg, 50 mg/kg, 100 mg/kg, and 175 mg/kg. The dose limiting toxicity (DLT) assessment cycle for the study was 28 days with subjects receiving 2 doses of TB-403 at Day 1 and Day 15 respectively. After the DLT period, temozolomide or etoposide could be added to the subject's treatment regimen.

Evaluations for the response to TB-403 were made at the end of cycle 1 and every 2 cycles thereafter.

The key safety findings from the study were as follows:

- TB-403 was safe and well tolerated at all dose levels: no maximum tolerated dose (MTD) was reached
- TB-403 exposure of children is in accordance with the exposure of the drug in adults
- TB-403 exposure and concentration increased dose-proportionally over the dose range of 20-175 mg/kg

The key response findings were as follows:

- At the 3 highest dose levels of TB-403, 7 out of 8 of medulloblastoma patients had stable disease
- 4 medulloblastoma patients had prolonged stabilization of disease > 100 days

Exploratory biomarker analysis showed a decrease in plasma levels of free placental growth factor (PIGF) to undetectable levels at all doses of TB-403, with no apparent changes in other angiogenic or inflammatory factors.

The results of the Phase 1 study warrant further evaluation of TB-403 in pediatric subjects with relapsed or refractory medulloblastoma (MB).

Dr. Giselle Sholler, Chair at Beat Childhood Cancer Research Consortium, commented: "I am pleased that the Beat Childhood Cancer Research Consortium has been able to play a key role in this important study. The encouraging data that I presented at AACR show that treatment with TB-403 can produce a clinically meaningful response in a significant number of children with relapsed and refractory medulloblastoma. The encouraging results, in what is a very difficult to treat patient population, warrant further clinical investigation, and we at the Beat Childhood Cancer Research Consortium would be happy to play our role in any such effort."



PRESS RELEASE

TB-403 is a humanized monoclonal antibody against PIGF which is expressed in several types of cancer, including medulloblastoma. A paper in *Cell* (Cell, 152, 1065-76, 2013), highlighted that PIGF plays a role in the growth of medulloblastoma. The paper was based on preclinical research conducted by Prof Rakesh Jain from the Massachusetts General Hospital at Harvard (Boston) and the team of Prof Dr. Peter Carmeliet from the VIB/ KU Leuven.

Prof Dr. Peter Carmeliet from the VIB/ KU Leuven, added, *"I am pleased that our preclinical research showing that PIGF plays a key role in the growth of medulloblastoma has been confirmed in this Phase 1 clinical study with TB-403. I look forward to following the further clinical development of this novel PIGF inhibitor and am confident that it has the potential to benefit children suffering from this devastating brain cancer."*

Dr. Patrik De Haes, Executive Chairman of Oncurious said, *"I would like to thank everyone who has taken part in the execution of this successful study with TB-403, especially the patients and their families. The data that has been generated show that TB-403 could expand the treatment options for children with relapsed and refractory medulloblastoma. Meanwhile, Oncurious' international patent application, published with a positive indication on the patentability of the combination of TB-403 with etoposide or temozolomide, and expiring as late as 2040, puts Oncurious in a good position to evaluate potential partnering options for future development and manufacturing of TB-403."*

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About Oncurious

ONCURIOUS NV is a Belgium-based biotech company focused on developing innovative oncology treatments derived from a series of promising new targets that are designed to enhance T cell activity and migration and infiltration into resistant tumour sites, boosting the response to immunotherapy in the large numbers of patients who respond sub-optimally to existing treatment.

Oncurious is working on a series of novel immuno-modulatory targets offering the potential to overcome tumor resistance mechanisms, which current immune checkpoint inhibitors cannot address, and thereby significantly enhancing the responses to immunotherapy across multiple tumor types. The team has discovered a potent and diverse panel of leads targeting human CCR8 and is entering the final stage of preclinical candidate selection.

Oncurious is majority owned by Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing next generation standard ophthalmic therapies designed to better preserve vision in patients with retinal vascular disorders, and VIB. Oncurious notes that BioInvent AB contributed to the initial stages of the trial, holding some co-rights to the project.

More information: www.oncurious.com



PRESS RELEASE

About VIB

VIB is a strategic research center in life sciences and biotech. The results of VIB's top research are actively translated into added value for society. VIB unites the expertise of 81 research groups thematically organized into 8 research centers. VIB's technology transfer team proactively translates new biological findings into new economic activities, such as starting up new companies and partnerships with the biotech and pharmaceutical industry. Since its foundation in 1996, VIB has created 20 start-up companies. VIB also engages actively in the public debate on biotechnology by developing and disseminating a wide range of science-based information about all aspects of biotechnology. VIB has a close partnership with five Flemish universities – Ghent University, KU Leuven, University of Antwerp, Vrije Universiteit Brussel and Hasselt University.

More information: www.vib.be