

Oncurious NV Announces FDA Acceptance of Investigational New Drug (IND) Application for a Phase I/IIa Study with TB-403 for the Treatment of Pediatric Brain Tumors

Study planned to start in Q1 2016

Leuven, Belgium – 7 January 2016 - Oncurious NV, an oncology company focused on the development of innovative medicines for the treatment of pediatric tumors, 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 Investigational New Drug (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 affect 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 (PIGF) which is expressed in several types of cancer, including medulloblastoma. High expression of the PIGF 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 rhabdomyosarcoma.

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

Dr Patrik De Haes, Executive Chairman of Oncurious commented, *“We are delighted that the FDA has accepted our IND for TB-403. This is a major milestone for Oncurious and paves the way for us to commence a Phase I/IIa study evaluating TB-403 in a range of rare pediatric brain cancers in the coming months. Based on the pre-clinical data that has been generated we are optimistic that this novel antibody could provide pediatric oncologists with a better treatment option for children afflicted with these life-threatening tumors.”*

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Press release

Oncurious NV is an oncology company focused on the development of innovative medicines for the treatment of pediatric tumors. Oncurious is a joint 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 in patients with Relapsed or Refractory Medulloblastoma. This is a rare, life-threatening brain tumor that mainly affect children. Enrolment of the first patient is expected in Q1 2016.

BioInvent International is Oncurious' co-development partner for the planned Phase I/IIa TB-403 clinical trial.

More information on Oncurious can be found at www.oncurious.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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