



FOR IMMEDIATE RELEASE

to-BBB Receives IND Approval for Novel Brain Cancer Drug, 2B3-101

Company Proceeds Into Phase IIa Clinical Trials With Inclusion of US Medical Centers

Leiden, the Netherlands, 19 August 2013 - [to-BBB](#), the brain drug delivery company, is pleased to announce the successful completion of its 2B3-101 Phase I part of its clinical trial in brain cancer patients, safely reaching clinically effective dosages. to-BBB is now ready to proceed to the Phase IIa part of this trial, treating patients with brain metastases from breast cancer, small cell lung cancer and melanomas, as well as patients with primary, malignant brain cancers (recurrent gliomas). With no commercially available treatments for brain metastases of solid tumors and no effective treatment alternatives in recurrent gliomas, 2B3-101 is targeting a high unmet medical need.

to-BBB is applying its proprietary [G-Technology](#)[®] to enhance the delivery of the anti-cancer drug, doxorubicin, to the brain as its internal lead product 2B3-101. [This study](#) with 2B3-101 is being performed in close collaboration with eight specialized clinics in the Netherlands, Belgium and France. to-BBB is currently planning to open an additional study site in the US, specialized in the treatment of patients with brain metastases. to-BBB submitted an IND application (investigational new drug) to the FDA in July and is now delighted to announce the approval of the IND from the FDA. The IND approval opens up opportunities to involve US medical centers in the development of 2B3-101.

“We are very enthusiastic about the positive results of our Phase I study so far, including a safety profile that is in line with our expectations and encouraging signs of anti-tumor activity,” says Fredrik Lonnqvist, CMO of to-BBB. “Consequently, we are very pleased that we are now ready to proceed to Phase IIa with the inclusion of US investigators in our clinical development program. We are excited about 2B3-101 in the potential treatment of brain metastases as well as primary brain cancers.”

“Breast cancer brain metastases present a challenge to both patients and clinicians as there are few systemic therapies capable of crossing the blood-brain barrier to control the disease,” says Dr. Carey Anders, co-director of the Multidisciplinary Brain Metastases Specialty Clinic at the University of North Carolina Lineberger Comprehensive Cancer Center. “I have had very positive experiences using liposomal doxorubicin in patients with advanced breast cancer, however efficacy in brain metastases can be limited due to less than optimal blood-brain barrier penetration. to-BBB provides a novel, promising technology that offers the potential to improve the current treatment paradigm for patients with intracranial breast cancer recurrences. Thus, I am pleased that the recent IND application has been approved by the FDA.”

The brain cancer indications targeted by 2B3-101 in the ongoing clinical trial affect at least 60,000 subjects in the US, and as many patients in Europe. In June 2013, the FDA together with the NBTS (National Brain Tumor Society) announced a “Clinical Trials Endpoint Initiative” to increase the volume and speed of approval for new treatments for this disease.

About to-BBB

to-BBB is a clinical stage biotechnology company focusing on enhanced drug delivery across the blood-brain barrier. The Company is developing novel treatments for devastating brain disorders, such as brain cancer and neuroinflammatory diseases, by combining existing drugs with the G-Technology[®], to-BBB's proprietary brain delivery platform. This technology combines the widely used drug delivery approach of pegylated liposomes with the endogenous tripeptide glutathione as targeting ligand in a novel and safe way. Together with several academic and pharma partners, to-BBB is investigating the versatility of the G-Technology[®] for drugs that are unable to reach the brain at systemically tolerable therapeutic doses. to-BBB is applying the G-Technology[®] to enhance the delivery of doxorubicin to the brain as its internal lead product 2B3-101 in a Phase I/IIa trial for the treatment of primary brain tumors as well as brain metastases. to-BBB's second product 2B3-201 combines methylprednisolone with the G-Technology[®] to treat neuroinflammatory diseases and is expected to enter a Phase I clinical study by the end of 2013.

to-BBB is headquartered in the Netherlands at the Leiden Bio Science Park and established a fully owned subsidiary, to-BBB Taiwan Ltd., in Taipei, Taiwan. Investors in to-BBB include Aescap Venture, Antea Participaties, Jonghoud International and the Industrial Bank of Taiwan Management Corporation (IBTM).

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