



FOR IMMEDIATE RELEASE

## to-BBB Presents Clinical Data on Lead Product 2B3-101

### *A Potential New Treatment Option for Patients with Brain Cancer*

Leiden, the Netherlands, 26 September 2013 - A novel drug for patients with brain cancer, 2B3-101, has shown preliminary positive results. The Dutch biotech [to-BBB](#) has developed 2B3-101 and initiated a clinical trial to investigate this new treatment. The Phase I safety results will be presented at the European Cancer Congress 2013 in Amsterdam at the end of September.

“This [first clinical trial](#) with 2B3-101 has focused on the safety of this new treatment, yet, promising signs of anti-tumor activity were observed in many of the patients at the higher dose levels tested,” says Dr. Dieta Brandsma from the Netherlands Cancer Institute - Antoni van Leeuwenhoek hospital (NKI-AVL).

The preliminary positive results from this clinical trial have warranted further investigation into the efficacy of 2B3-101. Thus, as a next step, four disease groups will be treated in the Phase IIa part of this trial, including patients with recurrent malignant gliomas, and patients with brain metastases from breast cancer, small cell lung cancer or melanomas.

Fredrik Lonnqvist, Chief Medical Officer at to-BBB, adds, “The prognosis for patients with brain cancer is usually poor, and there are very limited treatment options available. Therefore, we are committed to the continued evaluation of 2B3-101, based on the results seen so far.”

Results of this first clinical trial with 2B3-101 will be presented at the [European Cancer Congress 2013](#) (ECCO-ESMO-ESTRO) on the 30<sup>th</sup> of September. The safety of 2B3-101 was investigated both in patients with brain metastases from solid tumors and in patients with recurrent malignant gliomas. Patients that participated in this study were either refractory to standard therapy or unable to receive existing standard therapy. Adverse events reported during the study were all expected, and mainly related to transient bone marrow suppression, skin lesions (hand-foot syndrome) and mild to moderate infusion reactions. No signs of drug-related neurotoxicity and cardiotoxicity were observed. An additional 2B3-101 dose-escalation study in combination with Herceptin<sup>®</sup> is currently also about to be completed, which will allow inclusion of additional HER2+ breast cancer patients with brain metastases in the Phase IIa part of this trial.

The brain is a well-protected organ. The so-called blood-brain barrier selectively allows nutrients to enter the brain, and keeps harmful substances but also most drugs out of the brain. This makes treatment of brain tumors much more challenging compared to treatment of tumors outside the brain. By use of to-BBB's proprietary G-Technology<sup>®</sup>, the blood-to-brain delivery of drugs is enhanced by using active transport processes at the blood-brain barrier.

The 2B3-101 concept is based on the G-Technology and has previously been evaluated in non-clinical studies with promising results. In these studies, to-BBB has shown that conjugation of glutathione to the tips of pegylated liposomes can provide a five-fold increased delivery of doxorubicin to the brain compared to untargeted liposomes. In addition, treatment with 2B3-101 improved the survival of mice in an experimental model of brain cancer (glioblastoma) by 60%.

## **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).

**For more information,**

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