

PRESS RELEASE

FDA grants Orphan Drug Status for to-BBB's lead product

Leiden, August 23rd 2010

to-BBB, the Dutch brain drug delivery company, announces that the Food and Drug Administration (FDA) has granted orphan drug designation for to-BBB's brain cancer lead product 2B3-101.

As a proprietary brain-targeted version of the marketed product Caelyx[®]/Doxil[®] (PEG-liposomal doxorubicin), 2B3-101 uses glutathione (GSH) to safely enhance the delivery of doxorubicin across the blood-brain barrier. The therapeutic benefit and predictable safety profile of 2B3-101 has been successfully demonstrated in pre-clinical studies and the product is ready to start clinical testing in a phase I/II study. 2B3-101 can be developed for multiple brain cancer indications and to-BBB considers development for brain metastases of breast cancer as well as glioma.

Orphan drugs are developed for diseases which affect less than 200,000 people in the United States. The FDA has specifically granted the Orphan Drug Status of 2B3-101 for the treatment of glioma. This orphan drug designation qualifies to-BBB for an accelerated review process, tax credits, financial assistance for development costs, plus seven years of marketing exclusivity when 2B3-101 is approved by the FDA as treatment for glioma. The designation also allows for assistance in clinical trial protocol design. All these advantages will stimulate the development process of 2B3-101 for the treatment of glioma patients.

Recently, to-BBB has also received a positive opinion in the European Union by the Committee for Orphan Medicinal Products (COMP). With this additional approval by the FDA, the potential of to-BBB's lead product 2B3-101 for brain cancer patients around the world is further acknowledged.

About to-BBB

to-BBB is a Dutch biotechnology company in the field of enhanced drug delivery across the blood-brain barrier. The company is developing novel treatments for brain disorders by combining existing drugs with its proprietary brain drug delivery platform. The company's vision is that the treatment of currently unserved brain diseases will be best achieved by safely enhancing the blood-to-brain delivery of drugs.

to-BBB is headquartered in The Netherlands at the Leiden Bio Science Park and has established a fully owned subsidiary, to-BBB Taiwan Ltd., in Taipei, Taiwan.

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