

PRESS RELEASE

to-BBB receives positive opinion for Orphan Drug Designation

Leiden, June 14th 2010

to-BBB, the Dutch brain drug delivery company, has received a positive opinion from the Committee for Orphan Medicinal Products (COMP) on the orphan medicinal product designation for the company's brain cancer lead candidate 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 enter clinical trials end of 2010. The product can be developed for multiple brain cancer indications and to-BBB considers development for brain metastases of breast cancer as well as glioma.

The positive opinion for 2B3-101 by the COMP has specifically been granted for the treatment of glioma, which affects less than 5 per 10,000 people in the European Community. The low prevalence of this life-threatening condition makes drug development otherwise unappealing, especially for emerging biotech companies such as to-BBB. However, when the European Commission decides to grant the orphan drug status following the positive opinion of the COMP, to-BBB would receive additional market exclusivity for a period of ten years following approval of its drug candidate for this indication in Europe. Thereby the Orphan Drug Designation will increase the likelihood that 2B3-101 will become available for glioma patients.

“We thank the COMP for their positive opinion,” says Willem van Weperen, CEO of to-BBB. “We are excited about the potential of 2B3-101 and, supported by the benefits of the Orphan Drug Designation, we will continue to execute our strategy to develop this therapy for patients with life-threatening brain cancer.”

The Commission typically grants orphan drug status following a positive opinion from the COMP to a medicinal product intended for the diagnosis, prevention or treatment of a life-threatening or a chronically debilitating condition when the application for designation is submitted.

About the COMP

The Committee for Orphan Medicinal Products (COMP) is responsible for reviewing applications from persons or companies seeking 'orphan medicinal product designation' for products they intend to develop for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect not more than 5 in 10,000 persons in the European Union.

The COMP is also responsible for advising the European Commission on the establishment and development of a policy on orphan medicinal products in the EU, and assists the Commission in drawing up detailed guidelines and liaising internationally on matters relating to orphan medicinal products.

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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