FOR IMMEDIATE RELEASE

to-BBB Announces Positive Data from Phase 1 Clinical Study

-- Results from 2B3-201 Dose-ascending Trial Presented at Joint ACTRIMS/ECTRIMS Meeting--

Leiden, the Netherlands, September 12, 2014 – to-BBB, a biopharmaceutical company focusing on treatments for devastating brain diseases, today announced positive clinical data for its product candidate designed to treat neuroinflammation, 2B3-201, from an ongoing Phase 1 clinical trial in healthy volunteers and MS patients. The study was conducted in collaboration with the Center for Human Drug Research (CHDR), Leiden, the Netherlands. The results, presented Thursday, September 11, at the 2014 Joint ACTRIMS-ECTRIMS (Americas Committee and European Committee for Treatment and Research in Multiple Sclerosis) Meeting in Boston, provide evidence that 2B3-201 is safe and well-tolerated at therapeutic dose levels and has a greatly increased plasma half-life and prolonged effects supporting a single administration.

In the presented double-blind crossover Phase 1 clinical trial, a total of 18 healthy male subjects were divided over 3 cohorts and received ascending doses of 2B3-201 up to 450 mg, active comparator (free methylprednisolone, MP) up to 1000 mg or placebo (5% dextrose). The trial reported no serious adverse events (AEs) following single administration of 2B3-201 and all AEs reported were mild and self-limiting. The trial is currently expanded to include 18 additional healthy male and six additional healthy female subjects, as well as 18 MS patients.

“Based on evidence of extended half-life, long-lasting immunosuppressive effects and solid safety data, we are excited to move forward with a study expansion,” said Werner Gladdines, Head of Development at to-BBB. “Our goal is to deliver a safe and convenient therapeutic option with less side effects to MS patients.”

Dr. Anders Harfstrand, Chief Executive Officer of to-BBB added: “With these promising clinical results we have made a significant step forward towards proof of concept for both 2B3-201 and our pipeline developed from our G-Technology®.”

MS is a chronic disease of the CNS and relapses are characterized by acute neurological impairment. For these relapse events, standard of care are intravenous injections of high-dose MP at 500-1000 mg daily for 3 to 5 consecutive days. 2B3-201 consists of our proprietary glutathione PEGylated liposomal methylprednisolone (G-Technology®) and is designed to enable improved passage of the drug into the patient’s brain through single-dose treatment, reducing both dose and dosing frequency, ideally resulting in reduced side effects but with at least similar efficacy.

About to-BBB’s G-Technology®

to-BBB’s proprietary G-Technology® offers a way to safely enhance brain delivery of drugs that do not readily reach the brain within a favorable therapeutic window. G-Technology® is a drug delivery system that can carry a wide range of compounds in small vesicles, so-called liposomes, thereby protecting the body from side effects caused by peak drug concentrations. Two molecules, polyethylene glycol (PEG) and glutathione are attached to the liposomes to ensure a prolonged circulation time in the blood stream and to improve passage of the drugs across the blood-brain barrier.

About to-BBB

to-BBB is developing medicines for the treatment of devastating brain diseases. Our proprietary liposomal G-Technology® facilitates entry to the brain while simultaneously enabling sustained delivery of systemically administered therapeutics. Our technology has been shown to be compatible with approved as well as novel therapeutic entities. We have two clinical programs, one targeting multiple indications of brain cancers and the other neuroinflammatory diseases.

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