2-BBB announces joint venture in Taiwan with TTY Biopharm on its acute MS relapse program 2B3-201

Leiden, the Netherlands, April 11th 2017 – 2-BBB Medicines BV, a biopharmaceutical company focusing on treatments for devastating brain diseases, today announced to set up a Taiwan-based joint venture company with TTY Biopharm for the further clinical and commercial development of its product candidate designed to treat neuro-inflammation, 2B3-201, initially focused on patients with acute multiple sclerosis (MS) relapses.

End of last week, TTY Biopharm (Taiwan, TPEX code: 4105) announced the joint venture with the Dutch company 2-BBB with the aim to jointly develop the new liposomal drug product 2B3-201. TTY stated that the capital of the joint venture company was set at NT$ 360 million (€ 11.1 million) and TTY will invest NT$ 240 million (€ 7.4 million) in cash to obtain a 66.67% stake. 2-BBB will obtain a 33.33% stake in the new company for the exclusive 2B3-201-related patent rights and results valued at NT$ 120 million (€ 3.7 million). Furthermore, TTY will put another NT$ 260 million (€ 8 million) into TTY’s dedicated commercial-scale manufacturing infrastructure for 2B3-201, made available to the joint venture under an exclusive manufacturing agreement.

“I’m excited for the opportunity to set up and lead this Taiwanese joint venture company together with my long-term development partner TTY Biopharm. I believe that TTY’s cutting-edge development and manufacturing capabilities, in combination with the excellent access to the Taiwan financial market, gives an exceptional risk-reduced opportunity to further jointly develop and commercialize an effective treatment for neuro-inflammatory diseases,” says Dr. Pieter J. Gaillard, CEO of 2-BBB Medicines BV and the joint venture company. “2B3-201 will be developed up to market registration in two focused Phase 2/3 trials after completion of Phase 1 bridging studies using 2B3-201 with an optimized manufacturing and administration protocol,” Pieter Gaillard further commented.

“TTY has established itself as an international leading company for complex medicinal products and will provide the joint venture with the capabilities to fully exploit the commercial potential of 2B3-201 in a range of neuro-inflammatory diseases,” adds Sijme Zeilemaker, Head of Business at 2-BBB. “This further confirms the corporate development strategy and value of crucially improving existing drugs with the G-Technology®.”

About methylprednisolone in acute multiple sclerosis (MS) relapses and other neuro-inflammatory diseases
Solu-Medrol® (methylprednisolone) has become the standard of care for diseases with neuro-inflammation, such as acute MS relapses. As an acute pulse therapy, methylprednisolone treatment is given as a daily intravenous infusion of high doses (500-1000 mg) for 3-5 consecutive days. The therapeutic effect of a single injection of methylprednisolone has a relatively short duration, requiring the daily injections for at least 3 consecutive days. At these high doses methylprednisolone is effective, yet side effects like sodium retention-related weight gain and fluid retention, glucose intolerance with hyperglycemia, gastrointestinal side effects, and mood changes including insomnia and anxiety, occur frequently. All this is resulting in a substantial medical need among MS patients with acute relapses for a product with an improved safety profile and more convenient dosing regimen compared to the current standard of treatment drug Solu-Medrol®. In addition to acute MS relapses, there is comparable medical
need in related neuro-inflammatory diseases, such as optic neuritis, non-infectious uveitis, acute disseminated encephalomyelitis (ADEM), neuromyelitis optica (NMO), Behçet’s disease, as well as neuropathic pain, amyotrophic lateral sclerosis (ALS), Parkinson's disease and neuro-sarcoidosis.

About 2B3-201
2B3-201 (glutathione PEGylated liposomal methylprednisolone) is being developed for patients suffering from acute and chronic neuro-inflammatory diseases, with an initial focus on patients with acute MS relapses. 2-BBB's G-Technology® provides a safe method to enhance the slow and sustained delivery of drugs to the brain. By combining this technology with methylprednisolone, 2B3-201 was developed and tested in nonclinical models with neuro-inflammation, in which it showed a similar efficacy at single administration with a 10 times lower dose compared to multiple high doses of methylprednisolone, while reducing (CNS-related) side effects. 2-BBB has completed a double-blind crossover Phase I study with 2B3-201 in healthy male and female volunteers, studying the product in comparison to current methylprednisolone treatment and placebo. The study demonstrated evidence of extended half-life, long-lasting immunosuppressive effects and solid safety data, supportive of our goal to deliver a safe and convenient therapeutic option with less side effects to MS patients. 2B3-201 is expected to follow a relatively short route towards marketing authorization.

About 2-BBB’s G-Technology®
2-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, licensed-in from the Industrial Technology Research Institute (ITRI) of Taiwan, 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 2-BBB Medicines BV
2-BBB is created to develop medicines for the treatment of devastating brain diseases. We believe that we can transform the lives of those affected faster and more successful by combining known disease targets and compounds with established drug delivery systems united with safe targeting technology. This has led to two programs in clinical development: 2B3-101 for brain cancer and 2B3-201 for neuro-inflammatory diseases. 2-BBB is based in the Netherlands on the Leiden Bio Science Park, and its subsidiary to-BBB Taiwan Ltd. is based in Taipei, Taiwan.

About TTY Biopharm
TTY Biopharm Company Limited was established in 1960. For more than fifty years, TTY Biopharm has transformed from a production and sales oriented traditional generic drug pharmaceutical factory into development and marketing of branded generic drugs. With unending self-renovation and transformation, we utilize the experience, technology, and relationship network accumulated over the decades to seek improvement. Today, we redefine ourselves as a biotech company focusing on developing special formulations and new drugs. We hope to finally achieve our enterprise vision of “raising the quality of life for mankind through science and technology, and improving the status of Chinese people in the life industry worldwide.”
For further information, please contact

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