

Symbio Pharmaceuticals Limited

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Representative Director, President and Chief Executive Officer

SYMBIO PHARMACEUTICALS LTD. OBTAINS GLOBAL EXCLUSIVE RIGHTS FOR PEGYLATED ZINC PROTOPORPHYRIN (PEG-ZNPP) AGAINST GLEEVEC-RESISTANT LEUKEMIA CELLS

TOKYO, Sept 5, 2007 - Symbio Pharmaceuticals Limited has obtained exclusive global rights for research, development, manufacturing and marketing of its third drug candidate and new anticancer substance, poly(ethylene glycol)-conjugated zinc protoporphyrin (PEG-ZnPP), a water-soluble derivative of ZnPP. Effective against Gleevec-resistant CML and MCL, PEG-ZnPP has been developed by Professor Hiroshi Maeda and fellow scientists at Sojo University, where Prof. Maeda serves concurrently on the Faculty of Pharmaceutical Sciences, and as current chairman of The Japan Drug Delivery System Society. Symbio will search for a US partner having strong expertise in oncology and hematology.

PEG-ZnPP is a bio-functional molecule: it exhibits both an inhibitory effect on HSP32, and an enhanced permeability & retention effect (EPR). Prof. Maeda, in collaboration with Prof. Peter Valent at the Medical University of Vienna, discovered PEG-ZnPP's effect on HSP32. It exerts its anti-tumor effect by selectively inhibiting heme oxygenase activity (HO-1, also referred to as heat shock protein HSP32), leading to an increase in the production of toxic oxidants and eventual cancer cell death. Due to its EPR effect, PEG-ZnPP can selectively target tumor cells in vivo by preferentially accumulating in solid tumor tissue of mice, and remaining in such tissue for a prolonged period of time. Moreover, when excited by visible light, PEG-ZnPP produces active oxygen that can also damage tumor cells. In vitro studies have shown a strong cytostatic effect of this substance against Gleevec-resistant and chronic myeloid leukemia (CML) cells, and mast cell leukemia (MCL) cells. These findings suggest that therapeutic potential exists for treating Gleevec-resistant and sensitive CML and MCL patients, for which no effective therapy is currently available. In addition to the anti-tumor effect of PEG-ZnPP as a monotherapy, an additive and synergistic anti-tumor effect against general solid tumors (e.g. colon, head & neck, esophageal etc.) has been observed in concomitant use with other anticancer agents. Moreover, the use of PEG-ZnPP in combination with other cytotoxic agents such as cisplatin, camptothecin, doxorubicin, mitomycin C and etoposide, may reduce the required dose and subsequent side-effects of such agents. In preliminary safety studies with tumor-bearing mice, no adverse events were recorded with the use of an effective dose, suggesting that the substance is safe.

Symbio Pharmaceuticals was established with the corporate mission of addressing "underserved

therapeutic areas” having high medical need in Japan and the Asia Pacific Rim, and ultimately expediting the development and use of such drugs in a clinical setting. This corporate philosophy mirrors Professor Maeda’s approach to cancer chemotherapy, resulting in an agreement between both parties to jointly carry out research and development of PEG-ZnPP. Symbio Pharmaceuticals main focus lies in the development of drugs within three therapeutic areas: oncology, haematology and autoimmune disease. Symbio’s first in-licensed drug candidate, bendamustine hydrochloride, is currently under development for rituximab-refractory low-grade indolent non-Hodgkin’s lymphoma in Japan; to date, Phase I clinical studies have been completed with strong results, and preparations for Phase II are now underway (NDA approval targeted for 2011). Phase I preparations for Symbio’s second in-licensed drug candidate, an anti-emetic patch to be used as an adjunct to cancer therapy (AB1001), are ongoing with clinical testing to begin in early November of this year.

[Company Profile]

Established in March 2005 by Fuminori Yoshida, who previously served as both Corporate Vice President of Amgen Ltd. and President of Amgen Japan, Symbio reflects the philosophy of its management, “Creating Together, Living Together.” The company’s underlying goal is to foster a symbiotic relationship between the five major players of the healthcare industry: patients, doctors, scientists, regulatory agencies and investors. Through this symbiosis of key decision-makers, Symbio will be able to realize the fulfillment of unmet medical needs in Japan and the APAC, and meet all social and management responsibilities. Please see <http://www.symbiosis.co.jp> for detailed information on Symbio Pharmaceuticals.

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