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SymBio Pharmaceuticals Limited
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(Securities Code: 4582)

Initiation of Phase I Clinical Trial for Oral TREAKISYM® in Progressive Solid Tumors

TOKYO, Japan, January 22, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced today that it has initiated a Phase 1 study in Japan for oral TREAKISYM® in patients with progressive solid tumors.

SymBio holds approval for TREAKISYM® injectables which are already used for the treatment of three indications of malignant lymphoma (first-line and relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma, and chronic lymphocytic leukemia). The purpose of the Phase 1 study is to evaluate the recommended dose, dosage regimen, the tolerability[1] and the safety of oral TREAKISYM®, as it is a new formulation, and to identify types of solid tumors that show promise for treatment.

Based on the efficacy and safety data related to TREAKISYM® injectables that were demonstrated in the treatment of malignant lymphoma, the purpose of this study is also to provide a new treatment option for patients by developing the new oral formulation leveraging superior traits and fewer adverse events, including alopecia, compared with existing chemo therapy. Furthermore, SymBio will evaluate safer dosage regimes with no adverse effect on efficacy by leveraging the pharmacokinetic traits of the oral formulation, specifically, lowering Cmax and administration in lower doses during the treatment period. Oral formulation drugs can also be taken at home, eliminating the need for the patient to visit the hospital for intravenous infusion and reducing the treatment burden on the patient.

The development of oral TREAKISYM® is part of SymBio's strategy to develop a "TREAKISYM® platform." For TREAKISYM® injectables, the Phase III study for the indication of relapsed/refractory diffuse large B-cell lymphoma is underway. Although DLBCL accounts for the largest segment of malignant lymphoma in terms of patient numbers, currently only multiple drug therapies are available for r/r DLBCL. In addition, SymBio is deploying a sustainable growth strategy and will maximize the value of TREAKISYM® by significantly extending the product life through the development of TREAKISYM® liquid formulations (TREAKISYM® Ready-to-dilute and TREAKISYM® Rapid Infusion).[2]

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1. Tolerability refers to the degree to which overt adverse effects of a drug can be tolerated by a human subject.
2. Please see SymBio's press release of September 21, 2017: "Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to SymBio Pharmaceuticals Limited."

About TREAKISYM®

TREAKISYM® (non-proprietary name: bendamustine hydrochloride), a cytocide anti-cancer drug first used in Germany in the 1970s, is now widely used in more than 50 countries with indications for low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia.

Bendamustine is a unique compound having chemical properties of both an alkylating agent[3] and a metabolic antagonist[4], and a mode of action different from other anti-cancer drugs. It is expected that bendamustine, given its unique properties, could be effective for the treatment of solid tumors as well as malignant lymphoma. A number of clinical studies of bendamustine injectables have been conducted outside of Japan to explore this potential, with clinical efficacy reported for certain solid tumors, including breast cancer, small-cell lung cancer, and soft tissue sarcoma. Furthermore, clinical studies of oral bendamustine for multiple myeloma, low-grade non-Hodgkin's lymphoma, and chronic lymphocytic leukemia have indicated favorable results with respect to both safety and tolerability[3] of oral formulation.

- TREAKISYM® Intravenous Infusion 100 mg was approved in October, 2010 for manufacturing and marketing for the indication of relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan.
- TREAKISYM® was approved for the additional indication of chronic lymphocytic leukemia in Japan in August, 2016.
- TREAKISYM® Intravenous Infusion 25 mg, a standard low-dose product, was approved for manufacturing and marketing in Japan in September, 2016.
- TREAKISYM® was approved for the additional indication of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in December, 2016.

TREAKISYM® has been marketed through Eisai Co., Ltd. since December, 2010.

3. An alkylating agent is a type of cytotoxic anti-cancer drug. Alkylating agents inhibit DNA replication by attaching alkyl group sites to the DNA chain.
4. A metabolic antagonist is a type of cytotoxic anti-cancer drug. Metabolic antagonists prevent DNA replication and the growth and division of tumor cells by interfering with the utilization of substances produced in the metabolic process.

About SymBio Pharmaceuticals Limited

SymBio Pharmaceuticals Limited was established in March, 2005 by Fuminori Yoshida who previously served concurrently as Corporate VP of Amgen Inc. and founding President of Amgen Japan. In May, 2016 SymBio incorporated its wholly-owned subsidiary in the U.S., SymBio Pharma USA, Inc. (Headquarters: Menlo Park, California, President: Mr. Fuminori Yoshida). SymBio's underlying corporate mission is to "deliver hope to patients in need" as it aspires to be a leading global specialty biopharmaceutical company dedicated to addressing underserved medical needs with main therapeutic focus in oncology, hematology and pain management.