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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

First Patient Enrolled in Phase I Clinical Trial for Oral TREAKISYM® for Progressive Solid Tumors

TOKYO, Japan, May 28, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced the enrollment of the first patient in the Phase 1 study for oral TREAKISYM® in patients with progressive solid tumors,which was initiated on January 22, 2018.

TREAKISYM® is approved for three indications of malignant lymphoma (1st line and relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma, and chronic lymphocytic leukemia) and is currently used as treatment for numerous patients in each therapeutic area. The objective of this study is to investigate the recommended dose, dosage regimen, tolerability[1], and safety of a new oral formulation of TREAKISYM®, and to identify types of advanced solid tumors which show promise for treatment for future clinical trials. Solid tumors are cancers (excluding blood cancer) such as breast and lung cancer that form masses in organs and tissue. The category includes epithelial cell carcinomas which form in epithelial cells (internal organs), and non-epithelial cell carcinomas (sarcomas) which form in non-epithelial cells such as bone or muscle.

TREAKISYM® has been demonstrated by the clinical data to be effective and safe in the treatment of malignant lymphoma. It has superior properties, including fewer side effects (such as reduced hair loss) as well as efficacy. This study aims to make use of the benefits of TREAKISYM® in an oral formulation to provide a new treatment option for patients with solid tumor cancers. An oral formulation would also allow patients to take the drug at home, reducing the burden of outpatient visits.

The development of oral TREAKISYM® is part of SymBio's strategy to develop a TREAKISYM® platform. For TREAKISYM® injectables, a Phase III study for the indication of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) is underway ,which accounts for the largest segment of malignant lymphoma in terms of patient numbers, for which currently only multiple drug therapies are available. The Company is also planning a preclinical study of systemic lupus erythematosus (SLE). In addition, by significantly extending the product life of TREAKISYM® through the development of TREAKISYM® liquid formulations (TREAKISYM® Ready-to-Dilute and TREAKISYM® Rapid Infusion), SymBio aims to maximize business value through a sustainable growth strategy for TREAKISYM®.

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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[2] and a metabolic antagonist[3], 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 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.

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.

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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] 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.

[3] 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.