September 28, 2016
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Approval in Japan of the Anti-cancer Drug TREAKISYM® Intravenous Infusion 25 mg

TOKYO, Japan, September 28, 2016 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio,") announced today that TREAKISYM® Intravenous Infusion 25 mg, a standard low-dose product of the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride; "the Product") is now approved for manufacturing and marketing in Japan.

The Product, under the brand name of TREAKISYM® Intravenous Infusion 100 mg, was approved in October, 2010 for manufacturing and marketing for the indication of recurrent/refractory low-grade malignant non-Hodgkin's lymphoma and mantle cell lymphoma, and has been marketed through Eisai Co., Ltd. since December, 2010. Also, the Product has just been approved for the additional indication of chronic lymphocytic leukemia on August 26, 2016.

TREAKISYM® Intravenous Infusion 100 mg has been domestically marketed for about 6 years now, and used by many patients. It can now be used in combination with TREAKISYM® Intravenous Infusion 25 mg, a standard low-dose product, to enable selection of dosage more suitable for individual patients. This will also help reduce wastage of leftover drugs, which is expected to further contribute to the benefit of patients and healthcare providers.

In addition to these indications, in December, 2015, SymBio submitted a J-NDA for the first-line treatment of low-grade malignant non-Hodgkin's lymphoma and mantle cell lymphoma, which is currently being reviewed by the Pharmaceuticals and Medical Devices Agency. Also, a Phase 2 study in patients with recurrent/refractory advanced aggressive malignant non-Hodgkin's lymphoma has been completed.

SymBio will pursue the full range of use of the Product in an effort to maximize its value.

This approval of TREAKISYM® for injection, for intravenous infusion 25 mg, will not impact SymBio's current financial forecast.

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About TREAKISYM® (The underlined section is newly approved.)

Product name: TREAKISYM® for injection, for intravenous infusion 100 mg, 25 mg

Generic name: Bendamustine hydrochloride

Indications and usage:

1. Relapsed or refractory forms of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma
2. Chronic lymphocytic leukemia

Dosage and administration:

1. Relapsed or refractory forms of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma

   The recommended adult dose is bendamustine hydrochloride 120 mg/m^2 (body surface area) via 1-hour intravenous infusion once daily for 2 days on treatment, followed by 19 days off treatment, with repeated cycles. Dosage may be reduced as appropriate in accordance with the patient's condition.
2. Chronic lymphocytic leukemia

   The recommended adult dose is bendamustine hydrochloride 100 mg/m^2 (body surface area) via 1-hour intravenous infusion once daily for 2 days on treatment, followed by 26 days off treatment, with repeated cycles. Dosage may be reduced as appropriate in accordance with the patient's condition.

Dosage supply: 100 mg/1 vial, 25 mg/1 vial

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 the Company incorporated its wholly-owned subsidiary in the U.S., called SymBio Pharma USA, Inc. (Headquarters: Menlo Park, California, President: Mr. Fuminori Yoshida). The Company'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.