December 19, 2016
SymBio Pharmaceuticals Limited
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(Securities Code: 4582)

Approval in Japan of the Anti-cancer Drug TREAKISYM® for the Additional Indication of First-line Treatment of Low-grade Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma

TOKYO, Japan, December 19, 2016 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio,") announced today that TREAKISYM® Intravenous Infusion (non-proprietary name: bendamustine hydrochloride; "the Product") is now approved for the additional indication of first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma.

The Product has already been widely used in clinical practice since it was approved for manufacturing and marketing for the indication of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in October, 2010. SymBio obtained approval for the additional indication of the first-line treatment of this disease after filing an NDA in December, 2015, based on the results of a domestic Phase 2 clinical trial and the outcome of an overseas Phase 3 clinical trial on previously untreated patients.

In a clinical practice guideline in the U.S. and Europe, bendamustine-rituximab therapy is recommended as the main first-line treatment option for low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, where the Product is now widely used for that treatment. The Product awaited approval for the indication of first-line treatment of this disease in Japan while it had been designated as one of the "Unapproved or Off-Label Drugs with High Medical Needs" in response to requests from a patient group and relevant academic societies.

In an effort to address unmet medical needs, SymBio will pursue the proper use of the Product and maximize its product values.

Approval of this additional indication for first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma will not impact SymBio's current financial forecast for FY2016.

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About the related Overseas Phase 3 Clinical Trial

Bendamustine plus rituximab was compared with R-CHOP*1 in order to evaluate the efficacy and safety in treating previously untreated patients with indolent and mantle cell lymphoma in an open-label, multicentre, randomised, Phase 3 non-inferiority trial. The results of the study showed that median progression-free survival*2 was significantly longer in the bendamustine plus rituximab group than in the R-CHOP group, with fewer toxic effects*3.

* 1: Rituximab plus cyclophosphamide, hydroxydaunorubicin, oncovin/vincristine, and prednisone, the first-line standard of care

* 2: The time elapsed between treatment initiation and tumor progression or death from any cause

* 3: Rummel MJ, et al. Lancet 2013; 381: 1203

About Non-Hodgkin's Lymphoma

This is a group of blood cancers that includes all types of lymphoma except Hodgkin's lymphoma, where certain cells of the lymph system become cancerous. Non-Hodgkin's lymphoma accounts for the majority of lymphomas in Japan. Non-Hodgkin's lymphoma is categorized by progression speed; Lymphoma progressing in years is classified as low-grade, and in months or weeks as intermediate to high-grade.

SymBio estimates that the total number of patients in Japan with low-grade non-Hodgkin's lymphoma is around 11,800, of which 4,700 are in the recurrent/refractory category and 7,100 untreated, and thus eligible for first-line treatment.

About TREAKISYM®

From first use in Germany in the 1970s, TREAKISYM®, a cytocide anti-cancer drug, 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.

- 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 non-Hodgkin's lymphoma and mantle cell lymphoma in Japan, and has been marketed through Eisai Co., Ltd. since December, 2010.
- The Product 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.

<Product Description>

- Product name: TREAKISYM® for Intravenous Infusion 100 mg, 25 mg
- Generic name: bendamustine hydrochloride
- Indications and usage:
  1. Low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma
  2. Chronic lymphocytic leukemia
- Dosage and administration:
  1. Low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma

  (1) Untreated (first-line treatment)

  In combination with rituximab (genetic recombination), the recommended adult dose is bendamustine hydrochloride 90 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.

  (2) Relapsed or refractory forms

  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.

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.