

January 15, 2018
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

**Initiation of Patient Enrollment in the Phase 3 Clinical Trial
of the Anti-cancer Drug TREAKISYM®
for the Indication of relapsed/refractory diffuse large B-cell lymphoma**

TOKYO, Japan, January 15, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that the first patient has been enrolled in the Phase 3 study in Japan investigating the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride) for the indication of relapsed/refractory diffuse large B-cell lymphoma or r/r DLBCL.

The objective of the Phase 3 study is to confirm the efficacy and safety of the Phase 2 study. After successful completion of the Phase 3 study, SymBio aims to file an NDA for r/r DLBCL as an additional indication in the 2nd half of 2019.

SymBio aims to maximize the value of TREAKISYM® by continuing to pursue indication expansion and by extending the product life through the commercialization of Ready-to-dilute and Rapid Infusion liquid formulations*¹, the first of which SymBio plans to launch in the first half of 2021.

[Contact]

Investor Relations

Tel: +81 (0)3 5472 1125

*1. Please see 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 diffuse large B-cell lymphoma

Diffuse large B-cell lymphoma or DLBCL is a disease where large, malignant B-cell lymphocytes grow and develop into malignancy in lymph nodes and various organs. DLBCL is the most prevalent form of malignant lymphoma in Japan (30~40%), with patients in their 60s and 70s at peak onset age. As the majority of patients are elderly, patient numbers are expected to increase as Japan’s aging population continues to grow. Since the efficacy of current chemotherapy treatment is limited, patients with DLBCL who are resistant to chemotherapy or who relapse or are refractory to treatment, have an extremely poor prognosis, thus there is a strong need for new safe and effective drugs.

References:

- The Japanese Society for Lymphoreticular Tissue Research, Request for unapproved or off-label drugs, <http://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/gakkai3-2-5-1.pdf>
- Friedberg, JW. Relapsed/ refractory diffuse large B-cell lymphoma. ASH Education Book 2011 (1): 498-505

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.

- 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., called 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.