

April 8, 2019  
SymBio Pharmaceuticals Limited  
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(Securities Code: 4582)

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

TOKYO, Japan, April 8, 2019 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that it has completed enrollment of patients in its Phase 3 study of the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride) in relapsed/refractory diffuse large B-cell lymphoma ("r/r DLBCL").

The objective of the Phase 3 study is to confirm the efficacy and safety of bendamustine-rituximab combination therapy (BR therapy) for treatment of patients with r/r DLBCL. Progress in enrollment has steadily advanced since registration of the first patient in January 2018, and SymBio has now completed the patient enrollment target as revised pursuant to consultations with the Pharmaceuticals and Medical Devices Agency (PMDA). SymBio aims to file an NDA for r/r DLBCL as an additional indication for TREAKISYM® in the first half of 2020.

DLBCL accounts for the largest number of patients with malignant lymphoma in Japan, and r/r DLBCL in particular has no treatment options other than conventional combination therapy. Accordingly, with respect to r/r DLBCL, there is significant unmet medical need and patient advocacy groups have urged the Ministry of Health, Labor and Welfare (MHLW) to make the use of BR therapy available as soon as possible.

SymBio aims to achieve profitability in 2021, based in part on the approval of r/r DLBCL as an additional indication for TREAKISYM®. Through such label expansion, SymBio will continue to maximize the business value of TREAKISYM®.

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### **About diffuse large B-cell lymphoma**

Diffuse large B-cell lymphoma or DLBCL is a disease where large, malignant B-cell lymphocytes develop in the lymph nodes or in organs or other areas outside the lymph nodes. DLBCL is the most prevalent form of malignant lymphoma in Japan, accounting for between 30% and 40% of patients. As the majority of patients are elderly, with most patients in their 60s and 70s at the time of diagnosis, patient numbers are expected to increase as Japan's population continues to age. As the efficacy of current chemotherapy treatments is limited, and patients with DLBCL who are resistant to chemotherapy or who relapse or are refractory to treatment have an extremely poor prognosis, there is a high level of 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.
- SymBio currently has a Phase 3 clinical trial underway for r/r diffuse large B-cell lymphoma (r/r DLBCL), which has the largest number of malignant lymphoma patients, since August 2017.

SymBio is aiming to achieve annual sales of JPY 10 billion on a NHI drug price basis at the earliest possible stage.

### **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.