August 31, 2017
SymBio Pharmaceuticals Limited
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Initiation in Japan of the Phase 3 Clinical Trial of the Anti-cancer Drug TREAKISYM® for the Indication of relapsed/refractory diffuse large B-cell lymphoma

TOKYO, Japan, August 31, 2017 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio,") announced today that SymBio initiated a Phase 3 study ("the Study") in Japan of the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride; "the Product") for the indication of relapsed/refractory diffuse large B-cell lymphoma or r/r DLBCL.

Although DLBCL accounts for about one-third of malignant lymphoma in terms of patient numbers, a standard chemotherapy for treatment of DLBCL is currently not available, thus multiple drug therapies[*1] are administered. Multiple drug therapies, however, tend to have strong adverse effects, placing a burden on patients, and accordingly a new therapy is much-awaited.

Having completed a Phase 2 study for bendamustine-rituximab (BR) therapy, SymBio achieved remarkable clinical trial results[*2] for the treatment of patients with r/r DLBCL. Based on the achievements of this clinical study, BR therapy has been recommended in the NCCN Guidelines in the U.S., the standard for clinical policy in oncology, since 2012.

After consultation with The Pharmaceuticals and Medical Devices Agency (PMDA), SymBio has now initiated a Phase 3 study. The objective of the Study is to confirm the efficacy and safety of BR therapy.

r/r DLBCL falls under a therapeutic area with high unmet medical needs, where a new drug therapy is much-awaited, as the strong need for development of BR therapy has been voiced by a patient group and relevant academic societies.

Swiftly enrolling patients in the Study, SymBio aims to file an NDA for r/r DLBCL in the 2nd half of 2019.

This event will not impact SymBio's current financial forecast.

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*1. Multiple drug therapies are administered by way of a combination of multiple anti-cancer drugs with different modes of action. It is necessary to carefully select patients in light of safety, since multiple anti-cancer drugs with strong cytotoxic action such as myelosuppression are used in this therapy.

*2. An analysis of 59 cases in the Phase 2 study showed an ORR of 62.7% and CR of 37.3%.

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 new safe and effective drugs are long-awaited.

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
- Michinori Ogura, Treatment of elderly patients with malignant lymphoma *(Koreisha Akusei Rinpashu no Chiryou)*, Nippon Ronen Igakkai Zasshi 47: 271-275
- Friedberg, JW. relapsed/ refractory diffuse large cell B-cell lymphoma. ASH Education Book 2011 (1): 498-505

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 relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan.

- 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.
- 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.