April 28, 2021
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio receives approval for use of TREAKISYM® Ready-To-Dilute (RTD) Formulation in combination with rituximab for treatment of relapsed or refractory diffuse large B-cell lymphoma

TOKYO, Japan, April 28, 2021 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that it has obtained approval of a partial change to the Marketing Authorization of its anticancer agent TREAKISYM® ready-to-dilute ("RTD") liquid formulation which adds dosage and administration* (bendamustine hydrochloride 120mg/m^2) in combination with rituximab ("BR therapy") as treatment for relapsed or refractory diffuse large B-cell lymphoma ("r/r DLBCL").

Under the license agreement entered into between SymBio and Eagle Pharmaceuticals, Inc. (Headquarters: New Jersey, USA) in September 2017, SymBio obtained the exclusive rights to develop and commercialize the patent-protected ready-to-dilute ("RTD") and rapid infusion ("RI") liquid formulations of bendamustine hydrochloride in Japan, enabling SymBio to extend the product life of TREAKISYM® through 2031.

Statement from Fuminori Yoshida, President and CEO of SymBio: "This approval allows RTD, which is the next-generation formulation of TREAKISYM®, to be used for the treatment of relapsed or refractory DLBCL. The benefits of TREAKISYM® RTD are substantial as it significantly reduces the burden on healthcare providers compared to the lyophilized formulation.

SymBio is currently transitioning from a research and development business model to a profitability model, aiming to become a pharmaceutical company that is profitable and has growth potential. The first milestone in the SymBio's second inauguration is to achieve profitability in fiscal 2021, and obtaining approval of TREAKISYM® RTD for r/r DLBCL is a major step toward achieving this goal.

The Company will evaluate any financial impact of the information presented herein for the fiscal year ending December 2021 and make any required corresponding timely disclosures.

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*(NOTE)

[Indications]

Relapsed or refractory diffuse large B-cell lymphoma

[Dosage and administration]

- For concomitant use of rituximab (genetical recombination)

The usual adult dosage for intravenous drip infusion is 120mg/m^2 (body surface area) of bendamustine hydrochloride over an hour period once daily. Administration is performed daily for 2 days, and the drug is withdrawn for 19 days. This is followed by a single cycle with a maximum of 6 cycles.

About diffuse large B-cell lymphoma

Diffuse large B-cell lymphoma (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.

Based on the favorable clinical results of the Phase 2 study of BR therapy in relapsed/refractory diffuse large B-cell lymphoma ("r/r DLBCL") conducted by SymBio, BR therapy has been recommended in the National Comprehensive Cancer Network (NCCN) Guidelines in the United States since 2012.

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 rescue chemotherapy for relapsed or refractory DLBCL

Therapeutic relief chemotherapy is used for patients with hematopoietic tumors that do not respond to treatment (refractory) or that have relapsed. Currently, six to seven types of combination therapies are used as secondary treatment (rescue chemotherapy) for advanced diffuse large B-cell lymphoma in the event of recurrence, and most of them are combinations of multiple drugs (three to six drugs). For example, CHASE(R) is a combination of cyclophosphamide, cytarabine, dexamethasone, etoposide and rituximab, while ESHAP(R) is a combination of methylprednisolone, etoposide, cytarabine, cisplatin and rituximab. Both combination therapies are known to cause strong myelosuppression and increased toxicity in patients with relapsed or refractory DLBCL, many of who are elderly.

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® was approved for the additional indications of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in December 2016.
- SymBio achieved the primary endpoint (overall response rate) in Phase 3 study of TREAKISYM® in combination with rituximab as treatment for r/r DLBCL and obtained approval of a partial change application with respect to its marketing approval in March 2021.
- TREAKISYM® ready-to-dilute ("RTD") liquid formulation was approved in Japan in September 2020.
- SymBio aims 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.