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

Initiation of a phase 2 clinical trial of bendamustine and rituximab combination therapy followed by autologous hematopoietic stem cell transplantation in patients with relapsed or refractory diffuse large B-cell lymphoma

TOKYO, Japan, January 31 2022 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio" or the "Company") today announced that an investigator-led phase 2 clinical study to assess the efficacy and safety of bendamustine (TREAKISYM®) in combination with rituximab ("BR therapy") followed by autologous hematopoietic stem cell transplantation in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (the "Study") commenced on January 26, 2022, pursuant to a joint clinical research agreement between SymBio and Saitama Medical University. The Study is led by Dr. Yasuhito Terui, professor of Hematology Department at the Saitama Medical University Hospital.

TREAKISYM® was approved for marketing in BR therapy and with rituximab and polatuzumab vedotin ("P-BR therapy") in March 2021 for relapsed or refractory DLBCL. With this Study, we will further explore the clinical application of BR therapy in patients with relapsed or refractory DLBCL who are candidates for autologous hematopoietic stem-cell transplantation.

This Study was reviewed and approved by the nationally certified Clinical Research Review Board of Saga University, the administrators of Saitama Medical University, Saga University, and other participating institutions.

This Study was submitted to the Ministry of Health, Labour and Welfare and registered with the Japan Registry of Clinical Trials (jRCT), a database developed by the Ministry of Health, Labour and Welfare, and the information is published in jRCT.
https://jrct.niph.go.jp/latest-detail/jRCTs071210121

The Company does not expect the information presented herein to have any material impact on its financial outlook for the fiscal year ending December 2022.

[Contact]

Investor Relations
Tel: +81 (0)3 5472 1125

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, freeze-dried (FD) formulation, 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.
- TREAKISYM® ready-to-dilute (RTD) liquid formulation was approved in Japan in September 2020 for all the above indications.
- TREAKISYM® FD and RTD were approved for the additional indication of relapsed or refractory DLBCL in March 2021 and April 2021, respectively.

About autologous hematopoietic stem cell transplantation and relapsed or refractory 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. The long-term prognosis of patients with relapsed or relapsed DLBCL treated with conventional salvage chemotherapy alone is unsatisfactory. Following salvage chemotherapy, high-dose chemotherapy combined with autologous hematopoietic stem-cell transplantation (HDC/AHSCT) has been reported to improve the long-term prognosis. The Japanese Society of Hematology's Clinical Practice Guidelines of Hematopoietic Oncology recommend HDC/AHSCT for patients with relapsed or relapsed DLBCL aged 65 years or younger who respond to salvage chemotherapy (complete response + partial response).

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: Durham, North Carolina, 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.