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SymBio Pharmaceuticals Limited
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SymBio Announces Achievement of Primary Endpoint (Overall Response Rate) in Phase 3 Clinical Trial of TREAKISYM® in relapsed/refractory diffuse large B-cell lymphoma

TOKYO, Japan, November 5, 2019 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced favorable results from its Phase 3 study of the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride) in combination therapy with Rituximab ("BR Therapy") in relapsed/refractory diffuse large B-cell lymphoma ("r/r DLBCL"), with the overall response rate, which was the primary endpoint of the trial, exceeding expectations.

DLBCL accounts for the largest number of patients with malignant lymphoma in Japan, and r/r DLBCL specifically has a large number of elderly patients with no treatment options other than conventional combination therapy. Accordingly, there is a longstanding need for a superior therapy for r/r DLBCL, and patient advocacy groups have urged the Ministry of Health, Labour and Welfare to make BR therapy available as soon as possible.

SymBio plans to submit a New Drug Application (NDA) in the first half of 2020, after the completing the final analysis of the Phase 3 study. Together with the NDA submission for TREAKISYM® ready-to-dilute ("RTD") liquid formulation, announced in September 2019, and the continued efforts in establishing its own sales organization, SymBio is putting conditions in place to achieve profitability in 2021, which is a key management goal under the mid-range plan.

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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.

(Note on results of the Phase 2 study (59 patients): Overall response rate (ORR) 62.7%; Complete response (CR) 37.3%.)

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® 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 completed registration of the first patient in the Phase 3 clinical trial in Japan in April 2019. The primary objective of the trial is to confirm the safety of TREAKISYM® rapid infusion ("RI").
- SymBio submitted a New Drug Application ("NDA") for marketing authorization of TREAKISYM® ready-to-dilute ("RTD") liquid formulation in September 2019.

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.