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SymBio Pharmaceuticals Limited
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# Results of Phase III Trial of TREAKISYM® in Relapsed or Refractory Diffuse Large B-Cell Lymphoma

TOKYO, Japan, February 22, 2021 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced the results of phase III trial of the antineoplastic agent TREAKISYM® (bendamustine hydrochloride) in combination with rituximab ("BR therapy") for the treatment of relapsed or refractory diffuse large B-cell lymphoma ("relapsed or refractory DLBCL") at the 2021 the Japanese Society of Medical Oncology Annual Meeting (JSMO 2021 Virtual Congress).

A summary of the presentation is as follows:

Title (MO12-5)

Phase III trial of bendamustine plus rituximab for relapsed or refractory diffuse large b-cell lymphoma in Japan

Key results of the phase III trial (38 patients)

Overall response rate (CR+PR): 76.3%

Complete response (CR): 47.4%

Median overall survival (OS): 29.2 months

Statement from Fuminori Yoshida, President and CEO of SymBio: "Given the limited treatment options for relapsed or refractory DLBCL, conventional multi-drug combination therapy is currently used in Japan, and there has been demand from patients for a more effective option.
The key results of the phase III trial demonstrate the superior efficacy of bendamustine in relapsed or refractory DLBCL, and follow-up studies have shown that the median overall survival (OS) is 29.2 months. This is good news for patients."

For more information, please visit the 2021 the Japanese Society of Medical Oncology Annual Meeting (JSMO 2021 Virtual Congress) website at:
http://www.congre.co.jp/jsmo2021/en/index.html

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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 II study of BR therapy in relapsed/refractory diffuse large B-cell lymphoma ("r/r DLBCL") conducted by SymBio [Note], 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 II 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 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, who tend to be 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 III study of TREAKISYM® in combination with rituximab as treatment for r/r DLBCL and submitted a partial change application with respect to its marketing approval in May 2020.
- 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.