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SymBio Pharmaceuticals Limited
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The 25th Congress of the European Hematology Association ("25th EHA Annual Congress") Accepts Abstract for Phase III Clinical Trial of TREAKISYM® in Relapsed or Refractory Diffuse Large B-Cell Lymphoma for Publication

TOKYO, Japan, May 15, 2020 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced in November 2019 that it had achieved its primary endpoint (response rate) in a Phase III study 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"), and is pleased to announce that an abstract of the study has been accepted for publication by the Virtual Edition of the 25th EHA Annual Congress scheduled to be held in June 2020, as well as the official EHA journal's official library and virtual conference platform, including HemaSphere.

Abstract Title: EHA-1113 SINGLE ARM TRIAL OF BENDAMUSTINE IN COMBINATION WITH RITUXIMAB FOR RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA IN JAPAN

Key results of the phase III clinical trial (38 patients):

By gene activity pattern.

GCB type:	overall response rate ("ORR") 83%, complete response ("CR") 67%
Non-GCB type:	ORR 78%, CR 39%

By age group

Less than 65 years old:	ORR 86%, CR 71%
65 years of age or older but less than 75 years:	ORR 75%, CR 45%
75 years or older:	ORR 73%, CR 36%

For more information, please visit the 25th EHA Annual Congress website at:
https://ehaweb.org/congress/eha25/key-information-2/

Relapsed or refractory Diffuse Large B-Cell Lymphoma is one of the most common types of malignant lymphoma, and particularly for relapsed or refractory DLBCL, from the viewpoint of life prognosis, the development of new therapeutic agents are eagerly awaited. BR therapy is widely used in Europe and the United States for patients with relapsed or refractory DLBCL, and in Japan, patient advocacy and academic groups have submitted a request to Japan's Ministry of Health, Labour and Welfare to make BR therapy available as soon as possible for the treatment of relapsed or refractory DLBCL.

On May 14, the company submitted a partial amendment application for BR therapy for the treatment of relapsed or refractory DLBCL, which was accepted for review.

Contact

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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 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 III clinical trial in Japan in April 2019. The primary objective of the trial is to confirm the safety of TREAKISYM® rapid infusion.
- SymBio submitted a New Drug Application for marketing authorization of TREAKISYM® ready-to-dilute 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.