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SymBio Pharmaceuticals Limited
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(Securities Code: 4582)

SymBio receives approval for use of TREAKISYM® in combination with rituximab and polatuzumab vedotin as treatment for relapsed or refractory diffuse large B-cell lymphoma

TOKYO, Japan, March 23, 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® (non-proprietary name: bendamustine hydrochloride) for use of TREAKISYM® in combination with rituximab ("BR therapy") and polatuzumab vedotin as treatment for relapsed or refractory diffuse large B-cell lymphoma ("r/r DLBCL"). The approval applies to the 25 mg and 100 mg presentations of TREAKISYM® freeze-dried formulation.

Today Chugai Pharmaceutical Co., Ltd. (Headquarters: Tokyo, "Chugai Pharma") obtained approval for the use of polatuzumab vedotin in combination with bendamustine and rituximab in r/r DLBCL. SymBio obtained approval for the use of TREAKISYM® in combination with rituximab in r/r DLBCL based on the favorable results from SymBio's Phase 3 clinical trial in which the overall response rate, the primary endpoint of the trial, exceeded expectations. TREAKISYM® will be available for use in combination with BR Therapy and polatuzumab vedotin* following NHI price listing and launch of polatuzumab vedotin.
Given the limited treatment options for r/r DLBCL, multi-drug combination therapy is currently used as a rescue therapy in Japan, and there has been strong demand from patients for a more effective option with reduced side effects. Achieving profitability in fiscal year 2021 is the first milestone in the Company's second inauguration, and obtaining this approval for r/r DLBCL is a major step toward achieving this goal.

The Company plans to submit an application for partial change to the Marketing Authorization of TREAKISYM® for the use of TREAKISYM® ready-to-dilute (RTD) liquid formulation in combination with rituximab and polatuzumab vedotin as treatment for r/r DLBCL within the week of March 22, 2021.
The Company will evaluate any financial impact of the information presented herein for the fiscal year ending December 2021 and make any necessary corresponding timely disclosures.

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*(NOTE)

[Dosage and administration]

Relapsed or refractory diffuse large B-cell lymphoma

When rituximab (genetical recombination) and polatuzumab vedotin (genetical recombination) are used in combination.

The usual adult dosage for intravenous drip infusion is 90 mg/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. The dose may be adjusted according to the patient's condition.

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, 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 3 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.