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SymBio Pharmaceuticals Limited
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SymBio announces presentation of the final results of its Phase 3 Clinical Trial of TREAKISYM® in r/r DLBCL at the 83rd Annual Meeting of the Japanese Society of Hematology

TOKYO, Japan, September 29, 2021 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that the final results of its phase 3 trial of the anticancer drug TREAKISYM® (bendamustine hydrochloride) in combination with rituximab ("BR therapy"[1]; bendamustine hydrochloride 120mg/m^2) for the treatment of relapsed or refractory diffuse large B-cell lymphoma ("r/r DLBCL") were presented at the 83rd Annual Meeting of the Japanese Society of Hematology (held from September 23 to 25, 2021 in Sendai, Japan).

SymBio conducted a phase 3 study and a long-term follow-up study of BR therapy for relapsed or refractory DLBCL. The results confirmed the efficacy shown in a phase 2 study earlier conducted in Japan and Korea, and the final results were presented at the 83rd Annual Meeting of the Japanese Society of Hematology. The Company obtained regulatory approval of DLBCL as an additional indication for Treakisym in March of this year.

Key results of the phase 3 trial and a long-term follow-up study (38 patients)

- Overall response rate (CR+PR): 76.3%
- Complete response (CR): 47.4%
- Median overall survival (OS): 29.2 months

Given the limited treatment options for r/r DLBCL, the approval of BR therapy, and the approval of polatuzumab vedotin in combination with BR therapy (Pola-BR therapy[2] ;bendamustine hydrochloride 90mg/m^2) by Chugai Pharmaceutical Co., Ltd. (Headquarters: Tokyo), provide much-needed treatment options for patients.

For more information, please visit the 83rd Annual Meeting of the Japanese Society of Hematology website at: http://www.jshem.or.jp/83/en/index.html

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NOTE 1
[Dosage and administration]
For concomitant use of rituximab (genetical recombination)
The usual adult dosage for intravenous drip infusion is 120mg/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 Administration is performed daily for 2 days, and the drug is withdrawn for 19 days.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.
NOTE 2
[Dosage and administration]
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 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, 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 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.