March 8, 2022
SymBio Pharmaceuticals Limited
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SymBio announces publication the final results of its phase 3 clinical trial of TREAKISYM® in r/r DLBCL

TOKYO, Japan, March 8, 2022 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that the final results of its phase 3 clinical 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 published.

The final results of SymBio's phase 3 study and a long-term follow-up study of BR therapy for r/r DLBCL were published in *Annals of Hematology*. Based on the efficacy of BR therapy shown in this study, the Company obtained regulatory approval of DLBCL as an additional indication for TREAKISYM® in March 2021.

Key results of the 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 of polatuzumab vedotin in combination with BR therapy (Pola-BR therapy[2]; bendamustine hydrochloride 90mg/m^2) by Chugai Pharmaceutical Co., Ltd. (Headquarters: Tokyo), provides a much-needed treatment option for patients.

For more information, please visit the *Annals of Hematology* website at:
https://link.springer.com/article/10.1007/s00277-022-04801-2

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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 Administration is performed daily for 2 days, and the drug is withdrawn for 19 days.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 Administration is performed daily for 2 days, and the drug is withdrawn for 19 days.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 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.
- TREAKISYM® RTD to be added rapid infusion ("RI") or 10 minutes administration were approved in February 2022.

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: Durham, North Carolina, 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.