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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Chugai receives NHI price listing for polatuzumab vedotin for treatment of relapsed or refractory diffuse large B-cell lymphoma

TOKYO, Japan, May 19, 2021 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that Chugai Pharmaceutical Co., Ltd. (Headquarters: Tokyo, "Chugai") receives National Health Insurance (NHI) price listing for polatuzumab vedotin (genetical recombination) for the treatment of relapsed or refractory diffuse large B-cell lymphoma ("r/r DLBCL").

Chugai obtained approval for the use of polatuzumab vedotin in combination with bendamustine and rituximab ("Pola-BR therapy") in r/r DLBCL on March 23, 2021. As a result, TREAKISYM® becomes available for use in combination with BR therapy and polatuzumab vedotin* today.

Achieving profitability in fiscal year 2021 is the first milestone in the Company's second inauguration. The start of use of Pola-BR therapy for r/r DLBCL is a major step toward achieving this goal.

The Company will evaluate any financial impact of the information presented herein for the fiscal year ending December 2021 and make any required corresponding timely disclosures.

[Contact]
Investor Relations
Tel: +81 (0)3 5472 1125

*(NOTE)
[Indications]
Relapsed or refractory diffuse large B-cell lymphoma
[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 Administration is performed daily for 2 days, and the drug is withdrawn for 19 days.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 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 obtained approval of a partial change application with respect to its marketing approval in March 2021.
- 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.