March 26, 2019
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

TREAKISYM® Approved for use as a Pretreatment to Adoptive T-Cell Therapy

TOKYO, Japan, March 26, 2019 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio,") announced today that it has obtained a partial change to its marketing authorization for the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride), approving TREAKISYM® for use as a pretreatment to adoptive T-cell therapy.(1)

Today, Novartis Pharma K.K. (headquarters: Tokyo) obtained marketing approval for the first chimeric antigen receptor T-cell (CAR-T) therapy (Kymriah™) for the treatment of CD19 positive relapsed or refractory B-cell acute lymphoblastic leukemia (ALL) and CD19 positive relapsed or refractory diffuse large B-cell lymphoma (DLBCL).(2) After the launch of Kymriah™, TREAKISYM® may be used as a pretreatment agent for CAR-T therapy. In the area of adoptive T-cell therapy, an increasing number of new products are in development in Japan and in other countries, and TREAKISYM® now contributes to the treatment of patients in this expanding field.

As a standard therapy in the treatment of malignant lymphoma, TREAKISYM® is establishing its position as a backbone therapy, and the addition of new regenerative and gene therapies will further expand the use of TREAKISYM® in hematology.

(1) Adoptive T-cell therapy is a type of immunotherapy in which tumor-specific cytoxic T-cells are infused into cancer patients with the goal of recognizing, targeting and destroying tumor cells.
(2) Please refer to the press release issued by Novartis Pharma K.K. on March 26, 2019 at the following link: https://www.novartis.co.jp/news/news-archive

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

About TREAKISYM®

From first use in Germany in the 1970s, bendamustine hydrochloride, a cytocide anti-cancer drug, 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.

- Under the brand name of 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® Intravenous Infusion 25 mg, a standard low-dose product, was approved for manufacturing and marketing in Japan in September 2016.
- TREAKISYM® was approved for the additional indication of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in December 2016.

TREAKISYM® has been marketed through Eisai Co., Ltd. since December 2010.

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.