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

Launch of "Regenerative Medicine" Products that can be used with the anti-cancer drug TREAKISYM® as a pretreatment agent

TOKYO, Japan, May 22, 2019 -- Novartis Pharma K.K. (headquarters: Tokyo) today announced that the chimeric antigen receptor T-cell (CAR-T) therapy, KYMRIAH® (non-proprietary name: tisagenlecleucel), has obtained NHI Price Listing 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).
Novartis' press release: www.novartis.co.jp/news/news-archive

SymBio Pharmaceuticals Limited ("SymBio," headquarters: Tokyo) obtained a partial change approval for its anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride) on March 26, 2019. The approval provides a new treatment option to patients by enabling the use of TREAKISYM® as a pretreatment agent in Adoptive T-cell therapy (*).

TREAKISYM® was newly included as a standard-of-care option for low-grade B-cell non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia in the 2018 Guidelines for Tumors of Hematopoietic and Lymphoid Tissues, issued by JSH (Japan Society of Hematology) on July 20, 2018.

In addition to expanding the use of TREAKISYM® by obtaining approval for its use as a pretreatment agent, SymBio is currently conducting a Phase 3 study of TREAKISYM® in DLBCL. As TREAKISYM® increasingly establishes its position as standard therapy in the treatment of malignant lymphoma, SymBio will continue to expand the business to enhance corporate value.

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(*) Adoptive T-cell therapy is a type of immunotherapy in which tumor-specific cytoxic T-cells are infused into cancer patients for the purpose of targeting and destroying tumor cells.

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® 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.
- SymBio is conducting a Phase 3 clinical trial for r/r diffuse large B-cell lymphoma (r/r DLBCL), which has the largest number of malignant lymphoma patients. The trial began in August 2017.

SymBio is aiming 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.