September 27, 2018
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio files Partial Change Application for use of TREAKISYM® as a Pretreatment to Regenerative Medical Products

TOKYO, Japan, September 27, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio,") announced today that SymBio filed a partial change application to the marketing approval of SymBio's anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride) for use of TREAKISYM® as a pretreatment to regenerative medical products.

On April 23, 2018, Novartis Pharma K.K. (headquarters: Tokyo) filed for marketing approval for the first chimeric antigen receptor T-cell (CAR-T) therapy (product name in the United States and Europe: Kymriah™*) for the treatment of relapsed/refractory B-cell acute lymphoblastic leukemia (ALL) in patients aged 25 years or younger and relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in older patients. Upon approval of Kymriah™, TREAKISYM® may be used as a pretreatment agent for CAR-T therapy in these diseases. Various regenerative medical products are in development in Japan and in other countries. TREAKISYM® now contributes to the treatment of patients in the expanding field of regenerative medicine.

TREAKISYM® is becoming an established standard therapy for malignant lymphoma. Entering the new field of regenerative medicine will further strengthen the position of TREAKISYM® as the backbone treatment of malignant lymphoma.

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* For Kymriah™, please refer to the following press release issued by Novartis Pharma K.K. on the NDA for marketing approvals on April 23, 2018.
https://www.novartis.co.jp/news/media-releases/prkk20180423-1

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 with main therapeutic focus in oncology, hematology and pain management.