February 28, 2022
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio receives approval of TREAKISYM® Liquid Formulation Rapid Infusion (RI) administration

TOKYO, Japan, February 28, 2022 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that it received approval of a partial change to its Marketing Authorization for TREAKISYM® 100mg/4mL ready-to-dilute ("RTD") liquid formulation to add rapid infusion ("RI") administration.

Under the license agreement entered into between SymBio and Eagle Pharmaceuticals, Inc. (Headquarters: New Jersey, USA, "Eagle") in September 2017, SymBio obtained the exclusive rights to develop and commercialize the patent-protected liquid formulations of bendamustine hydrochloride (bendamustine HCl) in Japan. TREAKISYM® RTD was launched in January 2021.

The Company received approval of RI administration based on the results of its clinical study to investigate the safety and pharmacokinetics of the TREAKISYM® liquid formulation administered by 10-minute intravenous drip infusion. Similar to Eagle's BENDEKA®, which is currently marketed in the United States, TREAKISYM® RI administration can significantly reduce the burden on patients and healthcare professionals by reducing the infusion time from 60 minutes to 10 minutes.

Statement from Fuminori Yoshida, President and CEO of SymBio: "The TREAKISYM® liquid formulation RI administration was launched as BENDEKA® in the United States in 2016 and has been marketed for more than 5 years. With a dilution volume of approximately 50 ml, which is one-fifth of the current product, the infusion time is reduced to 10 minutes, and because it has and very low salt content, RI administration is suitable for patients with malignant lymphoma, many of who are elderly."

SymBio does not expect the information presented herein to have any material impact on its financial outlook for the fiscal year ending December 2022.

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About TREAKISYM® Liquid Formulation in the U.S. Market

In the United States, RI or the rapid infusion presentation of bendamustine hydrochloride injection was approved by the FDA in 2016 and is currently marketed in the U.S. by Teva Pharmaceutical Industries, Ltd. (Headquarters: Israel, "Teva") as BENDEKA® (bendamustine HCl) Injection. Sales in fiscal 2018 amounted to approximately 65 billion yen.

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 obtained approval for the marketing of TREAKISYM® Intravenous Drip Infusion 100mg/4mL (RTD, ready-to-dilute, liquid formulation) for all the above indications in September 2020.

 TREAKISYM® FD and RTD formulations were approved for the additional indication of relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) in March 2021 and April 2021, respectively.

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: 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 address underserved medical needs.