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SymBio Pharmaceuticals Limited
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Representative Director
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(Securities Code: 4582)

SymBio announces status of market adoption of the 10-minute Rapid Infusion (RI) administration of the TREAKISYM® Liquid Formulation

TOKYO, Japan, June 13, 2022 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced the status of market adoption of the rapid infusion (10-minute) administration of TREAKISYM® 100mg/4mL liquid formulation ("TREAKISYM® RI administration").

In September 2017, SymBio and Eagle Pharmaceuticals, Inc. (Headquarters: New Jersey, USA, "Eagle") entered into a license agreement whereby SymBio obtained the exclusive rights to develop and commercialize Eagle's patent-protected liquid formulation of bendamustine hydrochloride (bendamustine HCl) in Japan. The Company launched TREAKISYM® 100mg/4mL ready-to-dilute ("RTD") liquid formulation in Japan in January 2021. In February 2022, the Company received approval of TREAKISYM® RI administration based on the results of its clinical study to investigate the safety and pharmacokinetics of TREAKISYM® liquid formulation administered by 10-minute intravenous drip infusion (Study 2018001) and studies on the safety of the 10-minute intravenous drip infusion conducted outside Japan by Eagle (Study EGL-BDM-C-1301).

TREAKISYM® RI administration is identical to the product that is currently marketed in the United States under the trade name BENDEKA®, which was developed by Eagle as a formulation suitable for 10-minute administration and approved in the United States by the Food and Drug Administration (FDA) based on clinical studies conducted outside Japan. Compared to the conventional administration, TREAKISYM® RI administration has a lower infusion volume (approximately 50 ml vs. 250 ml) and a faster infusion time (10 minutes vs. 60 minutes). In addition to the significant benefits to patients and healthcare professionals resulting from TREAKISYM® RI administration's reduced infusion time, the lower infusion volume means the infusion has lower salt content which benefits patients with dietary sodium restrictions.

As of the end of May 2022, the Company's promotion plans for conversion of the market to TREAKISYM® RI administration were on track with 96% of major medical facilities reporting use of TREAKISYM® RI administration and more than 94% of all medical facilities indicating their intention to adopt TREAKISYM® RI administration.

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 administration 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.