March 25, 2020
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Completion of Patient Enrollment in Clinical Trial for TREAKISYM® Rapid Infusion

TOKYO, Japan, March 25, 2020 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that it has completed patient enrollment in a clinical study in Japan with the primary objective to confirm the safety of TREAKISYM® rapid infusion ("RI") product.

As a part of strategic life cycle management of TREAKISYM®, under the license agreement between SymBio and Eagle Pharmaceuticals, Inc. (Headquarters: New Jersey, USA) in September 2017, SymBio obtained the exclusive rights to develop and commercialize the patent-protected ready-to-dilute ("RTD") and RI liquid formulations of bendamustine hydrochloride in Japan. The liquid formulations extend the product life of TREAKISYM® through 2031*, further increasing the value of TREAKISYM® and setting the foundation for the Company's strategic growth. In addition to the RTD product, for which the new drug application ("NDA") for marketing authorization was submitted in September 2019, the RI product will reduce the infusion time from 60 minutes to 10 minutes, significantly benefitting both patients and healthcare providers.

SymBio plans to submit the NDA for RI and obtain approval in the second half of 2022. The application will include all indications for which TREAKISYM® is currently approved and relapsed/refractory diffuse large B-cell lymphoma ("r/r DLBCL"), for which the Company plans to submit an NDA towards the first half of 2020.

Fuminori Yoshida, President and Chief Executive Officer of SymBio, stated: "As RI, the next generation of TREAKISYM®, has exceptionally high added value and nearly 100% share in the U.S. market, we anticipate rapid market penetration in Japan. In addition, considering this formulation has a dilution volume of 50 ml, which is one-fifth of the current product, and low salt content, it will be easier for elderly patients to use. Extending the product life of TREAKISYM® through the patent protection period will further solidify the foundation for the growth of the Company."

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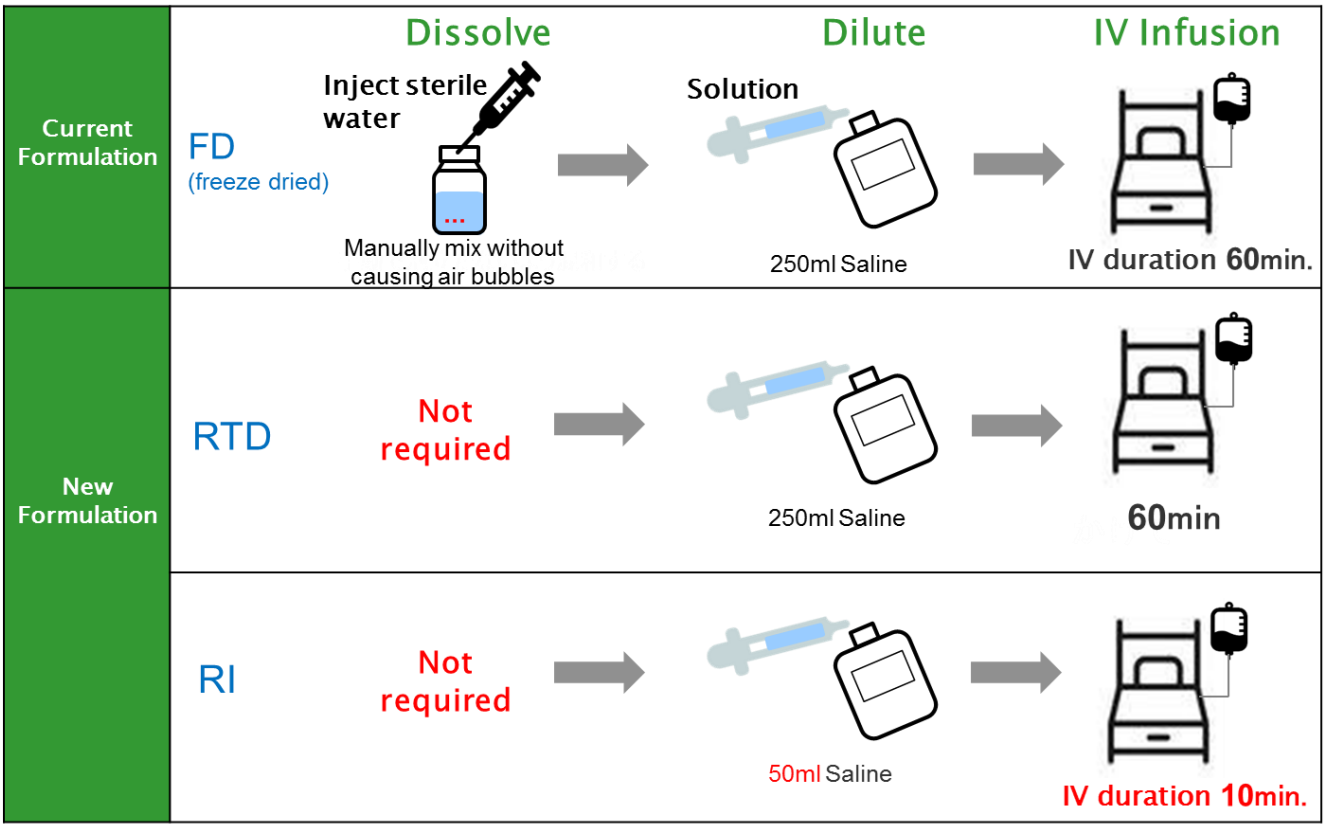
* See SymBio's press release dated September 21, 2017: *"Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to SymBio Pharmaceuticals Limited."*
https://www.symbiopharma.com/news_e/20170921_1e.pdf

About ready-to-dilute (RTD) and rapid infusion (RI) formulations

Unlike the current lyophilized formulation, RTD does not require complex manual reconstitution. The rapid infusion liquid formulation, RI, has the further advantage of reducing the administration time from 60 minutes (the administration time for the current lyophilized product) to 10 minutes, significantly benefitting both patients and healthcare professionals. In addition, the patent projection of the liquid formulations enable extension of the product life of TREAKISYM® through 2031. The equivalent product in the United States, Bendeka, was approved by the FDA in 2016 and is currently marketed in the U.S. by Teva Pharmaceutical Industries, Ltd. (Headquarters: Israel) with approximately 65 billion yen in sales in 2018.



About TREAKISYM®

From first use in Germany in the 1970s, TREAKISYM®, 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.

- TREAKISYM® Intravenous Infusion 100 mg was approved in Japan in October 2010 for the indications of relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma.
- 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 in Japan in September 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 initiated a Phase 3 clinical trial for r/r diffuse large B-cell lymphoma (DLBCL), which has the largest number of malignant lymphoma patients, in August 2017 and announced the achievement of a favorable response rate that exceeded expected levels, which represents a primary endpoint, in November 2019.

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.