April 10, 2019
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

First patient enrolled in Clinical Trial for TREAKISYM® Rapid Infusion Liquid Formulation

TOKYO, Japan, April 10, 2019 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that the first patient has been enrolled in a clinical study in Japan with the primary objective to confirm the safety of TREAKISYM® rapid infusion ("RI"), a liquid injection product with 10-minute administration time. The study has a planned enrollment of 36 patients, and the new drug application ("NDA") for TREAKISYM® RI will apply to all indications for which TREAKISYM® is currently approved in addition to relapsed/refractory diffuse large B-cell lymphoma ("r/r DLBCL") once r/r DLBCL is approved.

Under the license agreement entered into 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, enabling SymBio to extend the product life of TREAKISYM® through 2031.* As with the RTD product, for which the NDA submission is currently under preparation, RI is a liquid formulation product that does not require dissolution. In addition, RI will reduce the infusion time from 60 minutes (the infusion time for the current lyophilized product) to 10 minutes, significantly benefitting both patients and healthcare providers.

With respect to RTD, SymBio is currently preparing for and anticipates NDA submission in the third quarter of 2019, followed by launch of RTD in the first quarter of 2021. Launch of RI is planned in the first half of 2022, after completion of the clinical study to confirm its safety and securing regulatory approval.

Fuminori Yoshida, President and Chief Executive Officer of SymBio, stated: "The development of RTD and RI, the next-generation formulations of TREAKISYM®, is progressing well. Together with the application for the additional indication of r/r DLBCL which we plan to submit in the first half of 2020, it has become even more likely that SymBio will achieve profitability in 2021."

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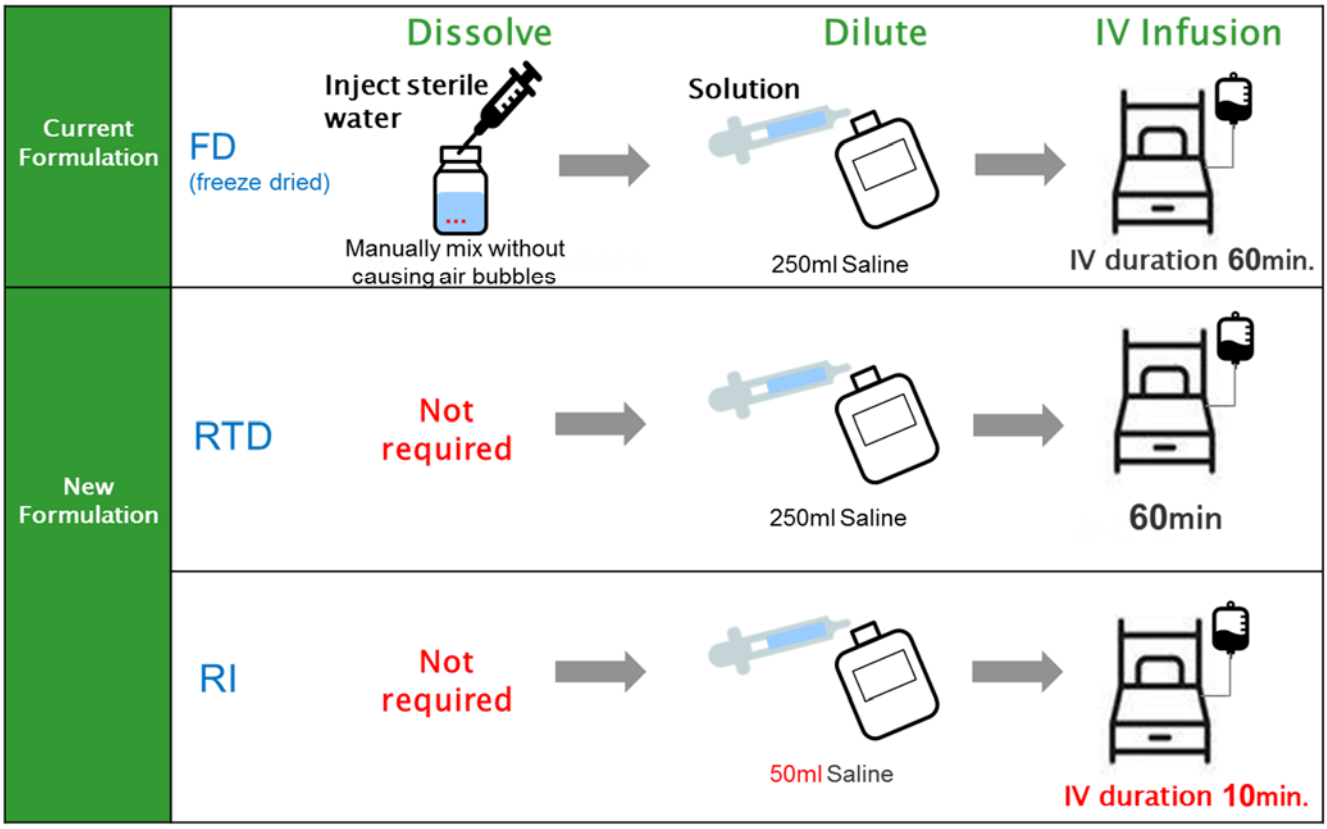
* See SymBio's press release dated September 21, 2017: *"Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to SymBio Pharmaceuticals Limited."*

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.



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 currently has a Phase 3 clinical trial underway for r/r diffuse large B-cell lymphoma (DLBCL), which has the largest number of malignant lymphoma patients.

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.