

September 9, 2020
Symbio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Last Patient Last Visit (“LPLV”) Achieved in Clinical Study for TREAKISYM® Rapid Infusion Liquid Formulation

TOKYO, Japan, September 9, 2020 -- Symbio Pharmaceuticals Limited (Headquarters: Tokyo, "Symbio") today announced that it has completed the observation period for all patients (LPLV) in its clinical study in Japan with the primary objective to confirm the safety of TREAKISYM® rapid infusion (“RI”), a bendamustine liquid injection product with 10-minute administration time.

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 RTD (ready-to-dilute) and RI liquid formulations of bendamustine hydrochloride in Japan, enabling Symbio to extend the product life of TREAKISYM® through 2031.* Similar to the RTD product, for which the new drug application (“NDA”) is currently under review for approval, 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 anticipates and is currently preparing for launch in the first quarter of 2021. RI approval is planned for the second half of 2022, after completion of the above-mentioned clinical study.

Symbio does not expect the information presented herein to have any material impact on its financial outlook for the fiscal year ending December 2020.

[Contact]

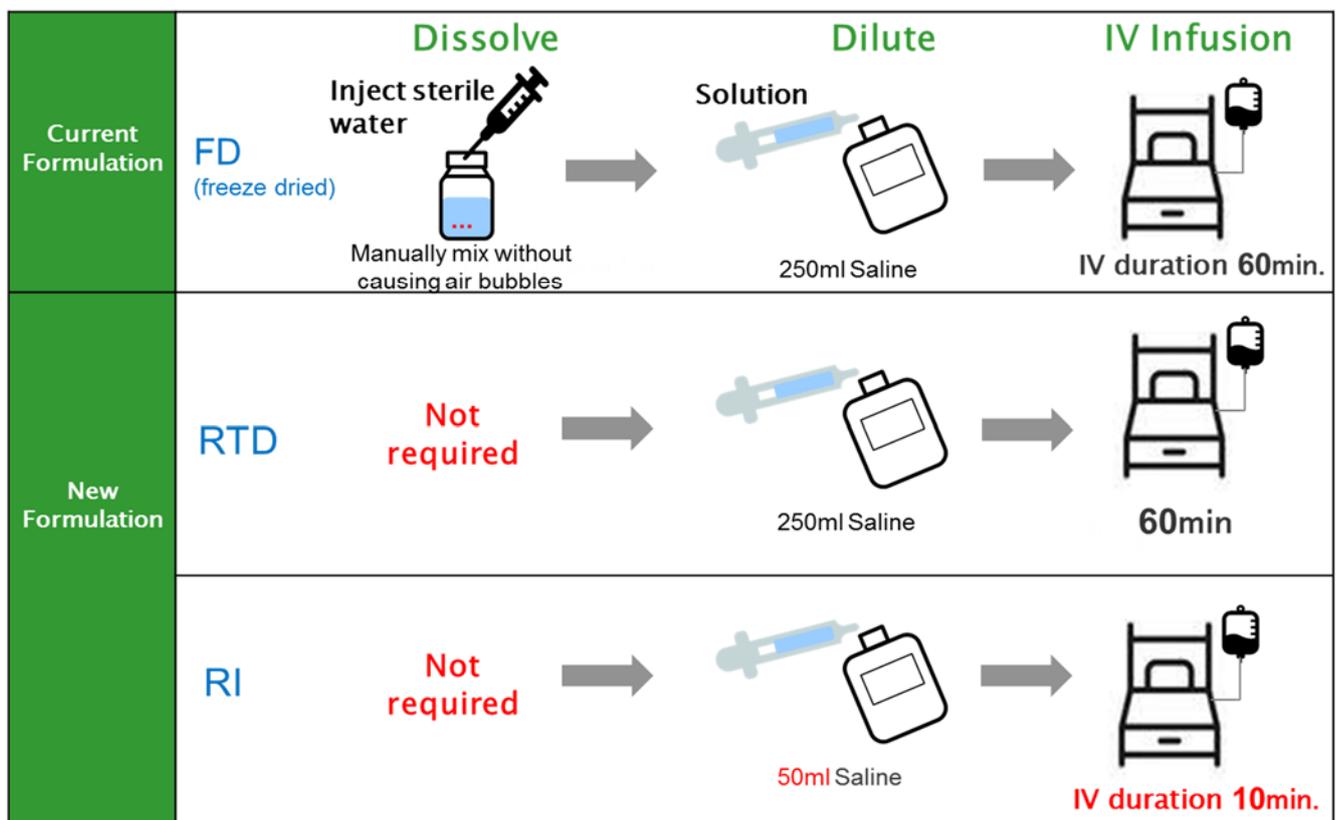
Investor Relations

Tel: +81 (0)3 5472 1125

* 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®

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 completed registration of the first patient in the Phase III clinical trial in Japan in April 2019. The primary objective of the trial is to confirm the safety of TREAKISYM® rapid infusion.
- SymBio submitted a New Drug Application for marketing authorization of TREAKISYM® ready-to-dilute liquid formulation in September 2019.

SymBio aims 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.