September 23, 2020
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Receives Approval of TREAKISYM® Ready-To-Dilute (RTD) Formulation

TOKYO, Japan, September 23, 2020 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that TREAKISYM® ready-to-dilute ("RTD") liquid formulation has been approved in Japan by the Pharmaceuticals and Medical Devices Agency ("PMDA").

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 rapid infusion ("RI") liquid formulations of bendamustine hydrochloride (bendamustine HCl) in Japan, enabling SymBio to extend the product life of TREAKISYM® through 2031.[1] Compared to the current lyophilized formulation of TREAKISYM®, the RTD and RI liquid formulations will bring significant benefits to patients and healthcare providers in Japan by eliminating the need for manual reconstitution and significantly reducing preparation time. SymBio plans to launch the RTD product in January 2021.

SymBio is also currently conducting a clinical trial with respect to safety of RI, the rapid infusion presentation of bendamustine HCl injection and has completed the observation period for all patients (LPLV) [2]. SymBio will apply for approval after completion of the study, aiming to receive approval in the second half of 2022. In the United States, the rapid infusion presentation of bendamustine hydrochloride injection was approved by the FDA in 2016 and is marketed in the U.S. by Teva Pharmaceutical Industries, Ltd. (Headquarters: Israel, "Teva") as Bendeka (bendamustine HCl) Injection.

Statement of Fuminori Yoshida, President and Chief Executive Officer of SymBio: "RTD and RI, which are the next-generation formulations of TREAKISYM®, will bring significant benefits to both patients and healthcare providers compared to the existing product. In addition, these new liquid formulations will enable SymBio to significantly extend the product life of TREAKISYM®. The approval of RTD is one of the key factors that will enable SymBio to meet its goal of achieving profitability in 2021. Together with the approval for the additional indication of r/r DLBCL which is currently under review by the PMDA, the pieces will be in place to enable SymBio to achieve this goal."

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

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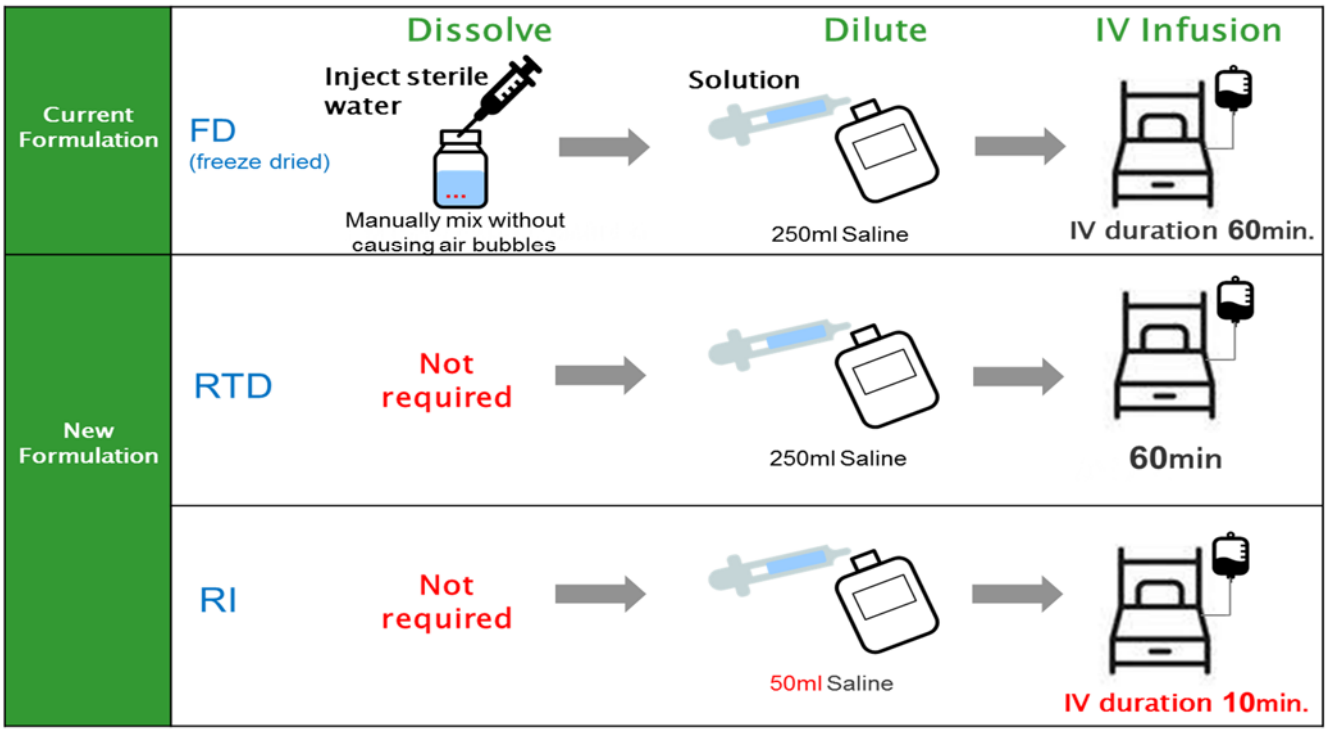
[1] See SymBio's press release dated September 21, 2017: *"Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to SymBio Pharmaceuticals Limited".*

[2] See SymBio's press release dated September 21, 2020: *"Last Patient Last Visit ("LPLV") Achieved in Clinical Study for TREAKISYM® Rapid Infusion Liquid Formulation".*

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.

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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. 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. 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).