

January 12, 2021
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Market Launch of TREAKISYM® Ready-To-Dilute (RTD) Formulation

TOKYO, Japan, January 12, 2021 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that TREAKISYM® ready-to-dilute liquid formulation ("RTD") launches in Japan today.

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.

Compared to the current lyophilized formulation of TREAKISYM®, the RTD liquid formulations will bring significant benefits to healthcare providers in Japan by eliminating the need for manual reconstitution and significantly reducing preparation time.

SymBio is also currently conducting a clinical trial with respect to safety of RI, the rapid infusion presentation of bendamustine HCl injection. SymBio will apply for approval after completion of the study this year. 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. With an infusion time of 10 minutes, RI will significantly lessen the burden on patients and healthcare professionals.

Statement of Fuminori Yoshida, President and Chief Executive Officer of SymBio: "The launch of RTD, the next-generation formulation of TREAKISYM®, will significantly extend the product life of TREAKISYM® and substantially benefit the business due to the improved profit margin compared to our current lyophilized product, and we will swiftly convert to the RTD formulation. In addition, by obtaining approval for the additional indication of relapsed or refractory diffuse large B-cell lymphoma ("r/r DLBCL"), which is currently under regulatory review, we are confident that we will be able to achieve profitability at an early stage."

SymBio does not expect the information presented herein to have any material impact on its financial outlook for the fiscal year ending December 2020. Performance forecasts for the fiscal year ending December 31, 2021 will be disclosed in the announcement of financial results summary for the fiscal year ending December 2020.

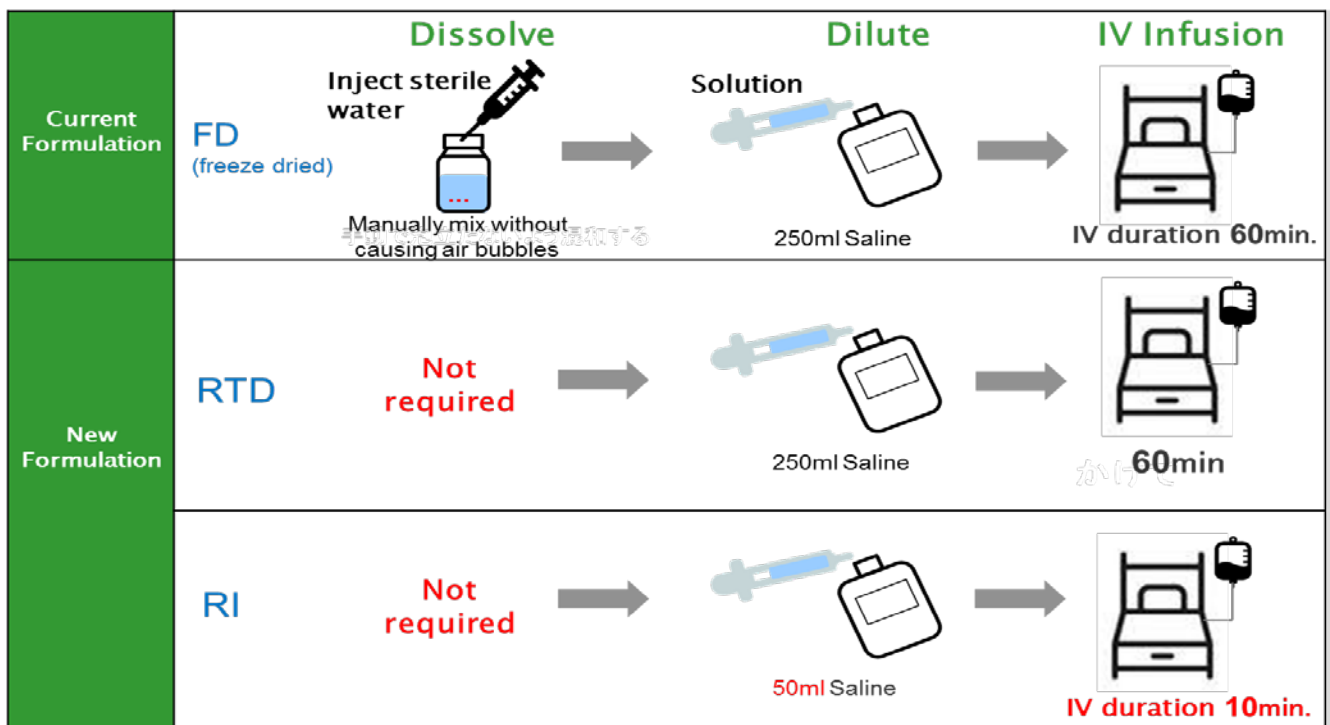
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About ready-to-dilute (RTD) and rapid infusion (RI) formulations

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 achieved the primary endpoint (overall response rate) in Phase III study of TREAKISYM® in combination with rituximab as treatment for r/r DLBCL and submitted a partial change application with respect to its marketing approval in May 2020.
- TREAKISYM® ready-to-dilute ("RTD") liquid formulation was approved in Japan in September 2020.
- 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.