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SymBio Pharmaceuticals Limited
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Representative Director
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(Securities Code: 4582)

SymBio Submits New Drug Application for TREAKISYM® Ready-To-Dilute (RTD) Formulation

TOKYO, Japan, September 26, 2019 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that it has submitted a New Drug Application ("NDA") for marketing authorization of TREAKISYM® ready-to-dilute ("RTD") liquid formulation. The NDA covers all indications for which TREAKISYM® is approved. In addition, a Phase 3 clinical trial for the additional indication of relapsed/refractory diffuse large B-cell lymphoma ("r/r DLBCL") is ongoing, and the NDA will cover the approval of RTD for r/r DLBCL once the indication 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 rapid infusion ("RI") liquid formulations of bendamustine hydrochloride in Japan, enabling SymBio to extend the product life of TREAKISYM® through 2031.* 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 will launch the RTD product in the first quarter of 2021, after obtaining marketing authorization.

Symbio is currently conducting a clinical trial on the safety of RI, a low-volume liquid formulation of bendamustine hydrochloride with a 10-minute infusion time (compared to the current 60 minutes). SymBio will apply for approval early after the study is complete, with the aim of launching the drug in the first half of 2022. In the United States, RI or the rapid infusion presentation of bendamustine hydrochloride injection was approved by the FDA in 2016 and is currently marketed in the U.S. by Teva Pharmaceutical Industries, Ltd. (Headquarters: Israel, "Teva") as Bendeka (bendamustine HCl) Injection.

Fuminori Yoshida, President and Chief Executive Officer of SymBio, stated: "The RTD product together with RI, which are the next-generation formulations of TREAKISYM®, have significant benefits which will dramatically reduce the burden on patients and healthcare providers, compared to the existing product. In addition, these new liquid formulations will enable SymBio to significantly

extend the product life TREAKISYM®, which will have an extremely positive impact on SymBio's corporate value. This NDA submission is the first step in a major leap forward toward SymBio's second inauguration. Together with another NDA for the additional indication of r/r DLBCL which we plan to submit in the first half of 2020, the probability that SymBio will become profitable in 2021 has increased."

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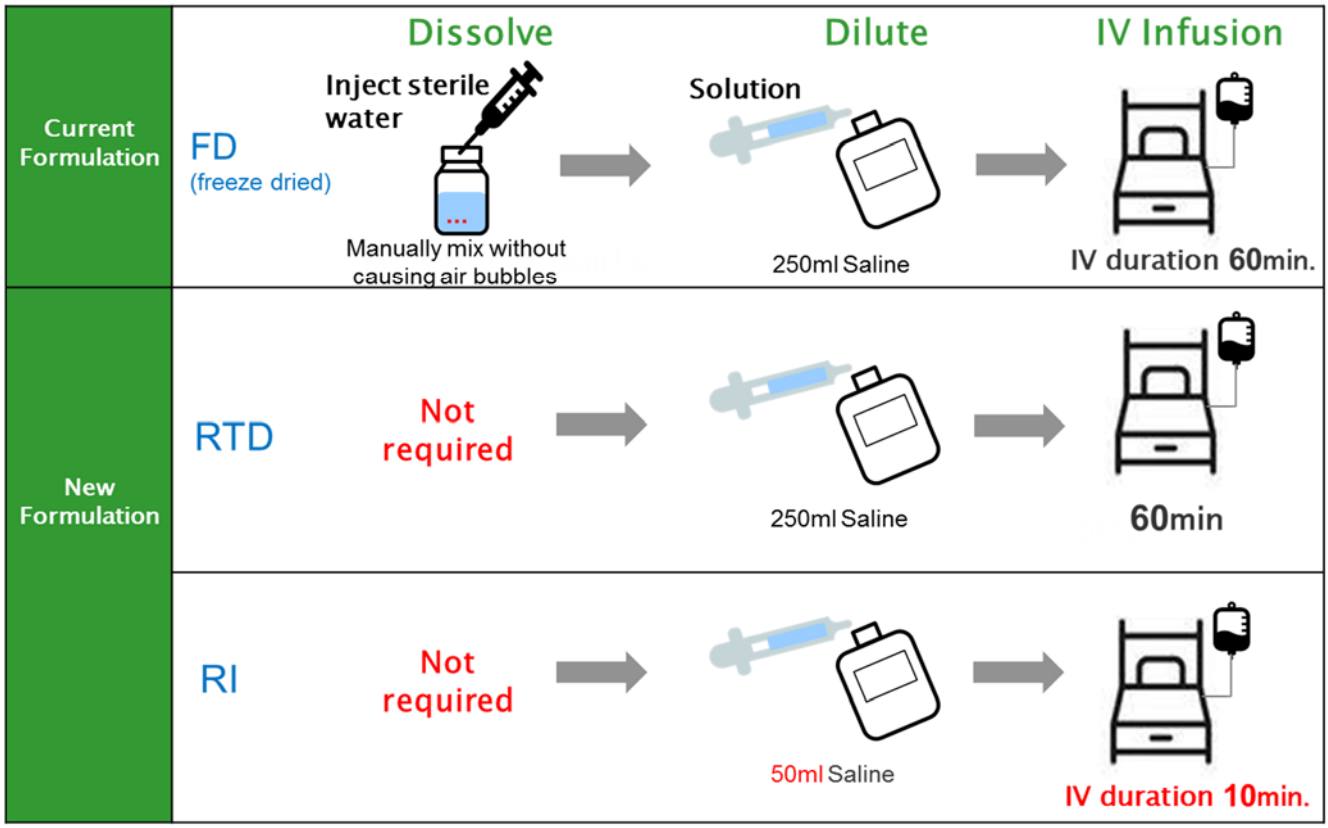
* See SymBio's press release dated September 21, 2017: *"Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to SymBio Pharmaceuticals Limited."*

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 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 began a Phase 3 clinical trial in August 2017 for r/r diffuse large B-cell lymphoma (DLBCL), which has the largest number of malignant lymphoma patients. SymBio completed the observation period of all patients (Last Patient/Last Visit, or "LPLV") in the trial in September 2019.
- SymBio will publish top-line results on efficacy in the fourth quarter of 2019, and aim to submit a New Drug Application (NDA) in the second quarter of 2020.

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. 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).