

November 30, 2018  
SymBio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer  
(Securities Code: 4582)

## **Clinical Trial Begins for TREAKISYM Liquid Formulation (Rapid Infusion Injection Formulation)**

TOKYO, Japan, November 30, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that SymBio has initiated a clinical study in Japan with the primary purpose to confirm the safety of TREAKISYM® rapid infusion liquid formulation ("RI"), an injection product with 10-minute administration time. The study will have a sample size of 36 patients. In addition to its applicability to all currently approved indications for TREAKISYM®, the study will apply to the approval of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) once granted.

In September 2017, SymBio entered into an licensing agreement with Eagle Pharmaceuticals, Inc. (Headquarters: New Jersey, USA) under which SymBio obtained the exclusive rights to develop and commercialize patent-protected liquid formulations of bendamustine hydrochloride (ready-to-dilute ("RTD") and RI liquid injection products) in Japan, enabling SymBio to extend the product life of TREAKISYM® through 2031.\* In addition to the RTD product, which is currently under preparation for NDA submission, the development of RI will reduce the administration time from 60 minutes (the administration time for the current lyophilized product) to 10 minutes, significantly benefitting both patients and healthcare providers.

SymBio is currently preparing an NDA submission for RTD and is aiming to launch of RTD in the first half of 2021. The launch of RI is planned for 2022, after the completion of the clinical study to confirm its safety and securing regulatory approval.

### **[Contact]**

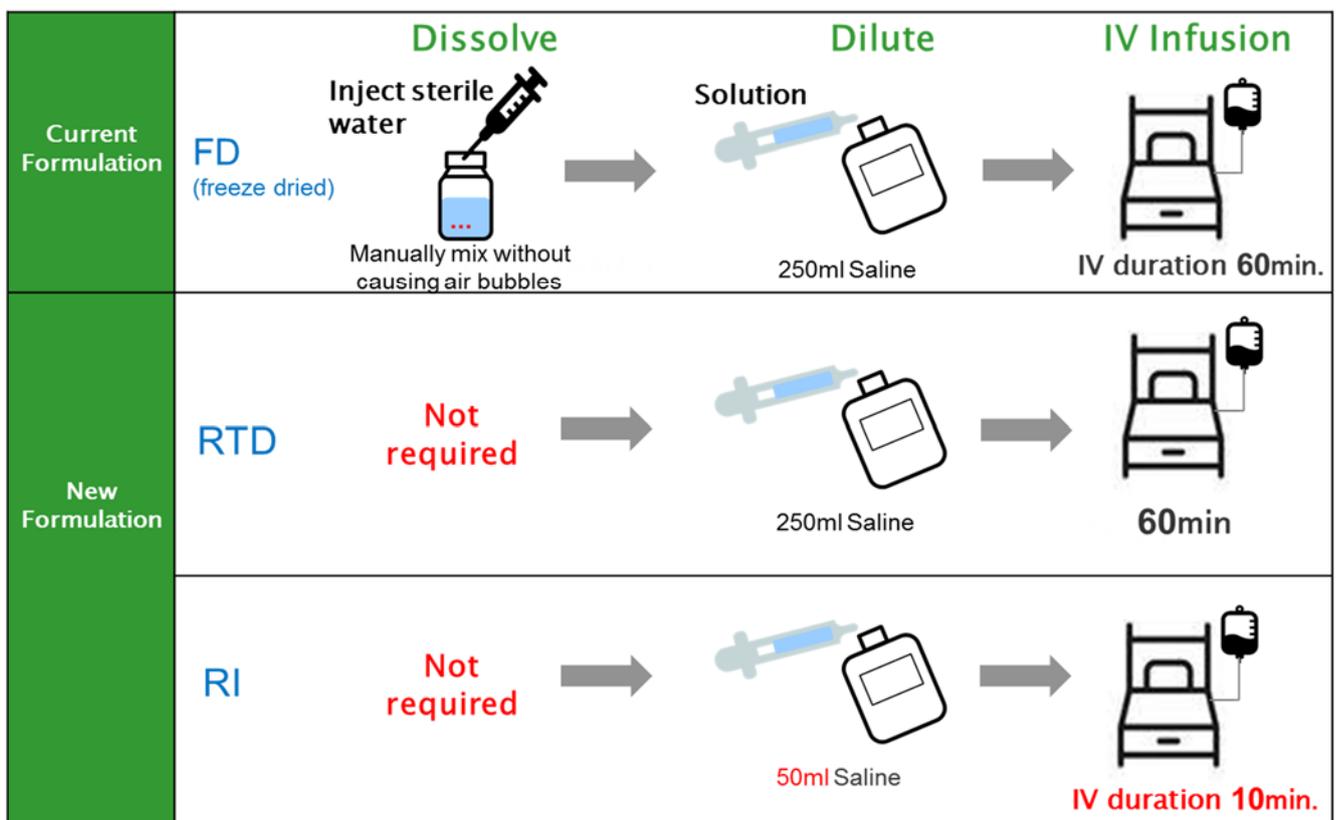
Investor Relations

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\* See Symbio’s September 21 2017 press release: "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 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 with main therapeutic focus in oncology, hematology and pain management.