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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
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(Securities Code: 4582)

Shipments of the 25mg Presentation of Anti-cancer Drug TREAKISYM®
Intravenous Infusion Paused and Shipment of Substitute

TOKYO, Japan, December 20, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced today that the import and sale of the 25mg presentation of TREAKISYM® Intravenous Infusion ("25mg"), a standard low-dosage form of the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride) was temporarily stopped. In September 2016, SymBio obtained marketing approval for 25mg in Japan in addition to the then already approved TREAKISYM® Intravenous Infusion 100mg ("100mg"). Both 25mg and 100mg are sold through Eisai Co., Ltd. (Headquarters: Tokyo, Japan).

A batch of 25mg product recently imported from Astellas Deutschland GmbH ("Astellas Deutschland"), a consolidated subsidiary of Astellas Pharma Inc. (Headquarters: Tokyo, Japan) was determined to be visually defective. SymBio has asked Astellas Deutschland to identify the root cause of the issue as soon as possible. As the cause has not been identified at this point, considering the health interests of patients, SymBio has decided to temporarily stop the import of 25mg presentation and has requested that Astellas Deutschland provide the appropriate quality assurances. SymBio is taking steps to normalize the supply as soon as possible and will issue another press release once it is determined when the import of 25mg will resume. As a temporary measure, SymBio will ensure the stability of TREAKISYM® supply by replacing 25mg with 100mg presentation. Further steps are being considered in coordination with Astellas Deutschland.

The impact on financial performance is being assessed. SymBio's financial forecasts for 2018 are unchanged.

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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 initiated a clinical trial to confirm the safety of TREAKISYM® liquid formulation (RI : Rapid Infusion Injection Formulation) in November 2018.

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.