



August 30, 2017 SymBio Pharmaceuticals Limited Fuminori Yoshida Representative Director President and Chief Executive Officer (Securities Code: 4582)

Application for Partial Change of Marketing Approvals for the Anti-cancer Drug TREAKISYM®

TOKYO, Japan, August 30, 2017 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio,") announced today that SymBio filed an application for the partial change of marketing approvals (the Application) for the anti-cancer drug TREAKISYM® (non-proprietary name: bendamustine hydrochloride; "the Product").

Aiming to provide more treatment options for patients, SymBio, through the Application, intends to have the Product approved for combination therapy with other anti-cancer drugs, in addition to already used rituximab (genetical recombination). On August 23, 2017, Chugai Pharmaceutical Co., Ltd. (Headquarters: Tokyo) filed a new drug application (NDA) for obinutuzumab (genetical recombination). If both this NDA and the Application are approved, the combination therapy of the Product with obinutuzumab will become available for patients.

This event will not impact SymBio's current financial forecast.





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*1. For obinutuzumab, please refer to the following press release issued by Chugai Pharmaceutical Co., Ltd. and Nippon Shinyaku Co., Ltd. on the NDA on August 23, 2017.

https://www.chugai-pharm.co.jp/news/detail/20170823150000.html

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.

- The Product, under the brand name of 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.
- The Product 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 for manufacturing and marketing in Japan in September, 2016.
- TREAKISYM® was approved for the additional indication of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in December, 2016.

TREAKISYM® has been marketed through Eisai Co., Ltd. since December, 2010.

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., called 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.