July 2, 2018
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
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(Securities Code: 4582)

TREAKISYM® Receives Approval for Combined Use with Anti-CD20 Antibodies

TOKYO, Japan, July 2, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, Japan; hereinafter referred to as "SymBio") announced today that it has obtained approval for a partial change to its marketing authorization for the anti-cancer agent TREAKISYM® (non-proprietary name: bendamustine hydrochloride).

In Europe and the United States, a significant number of new anti-CD20 antibodies (*1) are being developed for treatment of low-grade B-cell non-Hodgkin's lymphoma (low-grade NHL). The approval permits the use of TREAKISYM® in combination with rituximab or other new anti-CD20 antibodies and will expand the treatment options available to patients.

Today, Chugai Pharmaceutical Co., Ltd. (Headquarters: Tokyo) obtained marketing approval for GAZYVA® (non-proprietary name: obinutuzumab) (*2) for CD20 positive follicular lymphoma, a typical histologic type of low-grade NHL. After the launch of GAZYVA®, the approval will allow the combined use of TREAKISYM® and GAZYVA® for the treatment of CD20 positive follicular lymphoma.

In Japan, the market share for TREAKISYM® in the field of first-line treatrment of low-grade NHL is now more than 50%, as TREAKISYM® has steadily replaced the conventional standard therapy, R-CHOP. The approval for combination use with anti-CD20 antibodies will benefit patients with new treatment options and strengthen the position of TREAKISYM® as a standard therapy for the treatment of malignant lymphoma, further expanding SymBio's business and enhancing its enterprise value.

There is no change to the Company's earnings forecast for the year ended December 31, 2018.

(*1) CD20 is a transmembrane phosphoprotein that is a surface-membrane molecule specifically expressed on lymphocyte B cells. Anti-CD20 antibodies recognize and bind to CD20 in vivo, and target the binding to kill B cells by natural killer cells.

(*2) Refer to the Chugai Pharmaceutical Co., Ltd. and Nippon Shinyaku Co., Ltd. press release relating to GAZYVA® (non-proprietary name: obinutuzumab) dated July 2, 2018.
https://www.chugai-pharm.co.jp/english/news/detail/20180702150000.html

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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® 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 by SymBio through its partnership with 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.