



SymBio Pharmaceuticals Limited
San-Ei Building, 5-23-7 Shimbashi, Minato-ku, Tokyo 105-0004, Japan
Tel: +81-3-5472-1125 Fax: +81-3-5472-3054 <http://www.symbiopharma.com/>

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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer

SymBio Announces Japan NDA Approval of TREAKISYM® (Bendamustine Hydrochloride)

TOKYO, Japan, October 27, 2010 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, "SymBio") announced today that the Ministry of Health, Labor and Welfare (MHLW) has approved the Company's New Drug Application (NDA) for TREAKISYM® (SyB L-0501, bendamustine hydrochloride) for the treatment of refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. With this approval, TREAKISYM® presents a new treatment option for Japanese patients with difficult-to-treat cancers, thereby extending and improving quality of life.

TREAKISYM® is the first oncology drug in-licensed by SymBio (December, 2005), and developed for Japan and other Asia Pacific markets. Bendamustine hydrochloride has been used extensively in Germany for the treatment of non-Hodgkin's lymphoma, multiple myeloma and chronic lymphocytic leukemia, with the granting of market authorizations in a number of EU countries this year. In the US, Cephalon has been marketing the drug after receiving FDA approval for the treatment of patients with chronic lymphocytic leukemia, and indolent B-cell non-Hodgkin's lymphoma in 2008.

Flawless execution and nimbleness has enabled SymBio to shorten time to market for TREAKISYM®, only requiring 5.5 years from the Company's inception to market approval despite the average two year lag in oncology launches in Japan versus the EU and US. SymBio concluded a license agreement with Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") in August, 2008 for the co-development and commercialization of bendamustine hydrochloride in Japan, and wishes to express its appreciation to everyone involved in the development and launch of TREAKISYM®.

As part of ongoing label expansion plans and in accordance with the License Agreement signed with Eisai, SymBio initiated two additional phase 2 studies for TREAKISYM® this year, with the start of an international collaborative phase 2 trial of bendamustine HCl in combination with rituximab for the treatment of refractory and relapsed aggressive NHL in Korea and Japan

(March), and phase 2 trial in first-line untreated multiple myeloma (July).

In Asia Pacific, bendamustine has been approved in Japan, Singapore, and Hong Kong as the Company aspires to be a leading Oncology Specialty Pharma in the region.

SymBio will continue to expand the use of TREAKISYM® in the hematology space as rapidly as possible in order to address the unmet medical needs of patients as its business presence in the Asia Pacific region continues to gain momentum, and key pieces of the Company's strategic development and commercialization plans in these markets fall into place with the achievement of important milestones.

Note to Editors

1. About Bendamustine Hydrochloride

Bendamustine was first synthesized in the former 'East Germany' by Jenapharm, and is currently marketed in Germany under the brand name of Ribomustin® as a treatment for non-Hodgkin's lymphoma, multiple myeloma and chronic lymphocytic leukemia. In the United States, the product has been approved by the U.S. Food and Drug Administration and is currently prescribed under the brand name TREANDA® for the treatment of chronic lymphocytic leukemia and relapsed indolent B-cell non-Hodgkin's lymphoma

SymBio Pharmaceuticals Limited originally acquired the exclusive right to develop and market bendamustine hydrochloride in Japan (December, 2005), followed by China, South Korea, Taiwan and Singapore (March, 2007) from Astellas Deutschland GmbH (Headquarters: Munich, Germany, formerly Astellas Pharma GmbH).

2. About TREAKISYM®

Product Name:

TREAKISYM® for Injection, for intravenous infusion 100 mg

Generic Name:

Bendamustine Hydrochloride

Indications and Usage:

For the treatment of relapsed or refractory forms of the following diseases:

- Low-grade B-cell non-Hodgkin's lymphoma
- Mantle cell lymphoma

Dosage and Administration:

- The usual adult dose of bendamustine hydrochloride is 120 mg/m² infused intravenously over 60 minutes on Days 1 and 2 of repeated 21-day cycles. The dose may be reduced appropriately according to the patient's condition.

3. About SymBio Pharmaceuticals Limited

SymBio Pharmaceuticals Ltd. was established in March, 2005 by Fuminori Yoshida, who previously served concurrently as Corporate VP of Amgen Ltd. and President of Amgen Japan

(currently Takeda Bio Development Center Limited). The company's underlying corporate mission is "delivering hope to patients in need" as it aspires to be a leading specialty pharmaceutical company in Asia Pacific dedicated to addressing underserved medical needs in the areas of oncology, hematology and autoimmune disease.

[Contact]

SymBio Pharmaceuticals Limited.

Hiroki Maekawa,

Board Director, Corporate Officer, Chief Financial Officer

Tel: +081(0)3 5472 1125

URL: <http://www.symbiopharma.com/>