

December 10, 2010
SymBio Pharmaceuticals Limited

SymBio Launches TREAKISYM® in Japan

TOKYO, Japan, December 10, 2010 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, “SymBio”) announced today the launch of TREAKISYM® (SyB L-0501, bendamustine hydrochloride) in Japan for the treatment of refractory/relapsed low-grade B-cell non-Hodgkin’s lymphoma and mantle cell lymphoma. This marks the achievement of a major corporate milestone in SymBio’s history, transforming the company into a biopharmaceutical company with solid product revenue in 2011.

In August, 2008, SymBio concluded a license agreement with Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) for the co-development and commercialization of TREAKISYM in Japan. In accordance with the agreement, Eisai has assembled a team of dedicated oncology-focused liaisons to oversee each major market area in Japan along with 1,400 medical reps to promote and detail TREAKISYM®.

TREAKISYM® is the first oncology drug in-licensed by SymBio (December, 2005) for development and commercialization in Japan and other key Asia Pacific markets. The Ministry of Health, Labour and Welfare (MHLW) approved the company’s New Drug Application for TREAKISYM® on October 27th this year. Flawless execution and nimbleness has enabled SymBio to shorten time to market for TREAKISYM®, only requiring 4 years from first patient enrolled to market approval. This short development timeline to market approval has enabled SymBio to markedly reduce the drug lag between the US launch of TREANDA® and Japan launch of TREAKISYM® to two years, and to almost zero drug lag between the European and Japan launches.

Fuminori Yoshida, President and CEO of SymBio, said, “I am extremely pleased that as a result of the dedication and commitment invested by our people at SymBio, we have succeeded in significantly shortening the drug lag between the launch of bendamustine in Japan and other countries to deliver this much-needed cancer drug to patients as early as possible. The availability of this drug in Japan will greatly help non-Hodgkin's lymphoma and mantle cell lymphoma patients who have suffered needlessly due to the lack of effective treatment. This major achievement embodies the culmination of our efforts since the company’s inception in 2005 with the corporate mission of addressing the unmet medical needs of patients.”

As part of ongoing label expansion plans and through its collaboration with Eisai for future development, SymBio initiated two additional phase 2 studies in 2010 for TREAKISYM®; enrollment is currently underway for a Japan-Korea joint phase 2 trial of bendamustine in combination with rituximab for the treatment of refractory and relapsed aggressive NHL, and as first-line treatment in a phase 2 trial in untreated multiple myeloma patients.

SymBio will continue to expand the use of TREAKISYM® in the hematology space as nimbly as possible in order to address the unmet medical needs of patients as its business presence in Asia Pacific continues to gain momentum, and key pieces of the company's strategic development and commercialization plan fall into place upon the completion of important milestones.

Note to Editors

1. About Bendamustine Hydrochloride

Bendamustine was first synthesized in the early 1960s in the former 'East Germany' by Jenapharm, and is currently marketed in Germany under the brand name "Ribomustin®" as a treatment for non-Hodgkin's lymphoma, multiple myeloma and chronic lymphocytic leukemia. Mundipharma received marketing authorizations in several EU countries this year for the drug under the brand name "Levact®." In the United States, the drug has been approved by the U.S. Food and Drug Administration and is marketed as 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 from Astellas Deutschland GmbH (Headquarters: Munich, Germany, formerly Astellas Pharma GmbH) to develop and commercialize bendamustine hydrochloride in Japan (December, 2005), followed by signature of a second license agreement for the exclusive right to China/HK, South Korea, Taiwan and Singapore (March, 2007).

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 indications:

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

Dosage and Administration:

- The standard 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 as deemed appropriate according to the patient's condition.

NHI Drug Price Standard: TREAKISYM® 100 mg 92,356 yen / vial

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 founding 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.

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