SymBio Pharmaceuticals Limited

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

TREAKISYM® Phase II Trial in Multiple Myeloma

TOKYO, Japan, October 31, 2013 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced the company`s decision to discontinue its phase II clinical trial in Japan for TREAKISYM® (bendamustine HCI, SyB L-0501) in refractory and relapsed multiple myeloma (r/r MM).

In collaboration with Eisai (Headquarters: Tokyo, "Eisai"), SymBio had been conducting the multicenter open-label trial in r/r MM patients with bendamustine as a monotherapy since December, 2011, as it continues to pursue the approval of additional indications for TREAKISYM®. While safety of the drug has been established in this study following the treatment of 17 patients at 90 mg/m^2, the study has failed to achieve the expected level of efficacy as a single agent. SymBio and Eisai will re-examine the development strategy for r/r MM in Japan in relation to the development status of TREAKISYM® in the US and EU where it is being used in combination with other anticancer drugs. TREAKISYM® is under development for frontline low-grade non-Hodgkin`s lymphoma (NHL), refractory and relapsed diffuse large B-cell lymphoma (r/r DLBCL) and frontline chronic lymphocytic leukemia (CLL) in Japan.

In Japan, SymBio received marketing approval for TREAKISYM® in October, 2010, for r/r low-grade NHL & mantle cell lymphoma (MCL), and the drug is being actively promoted and marketed by Eisai.

SymBio's financial forecast for FY 2013 and Long Range Plan will remain unchanged despite discontinuation of the r/r MM clinical program.

[Please read the following to learn more about TREAKISYM® and SymBio Pharmaceuticals]

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Note to Editors

Glossary

1 non-Hodgkin's lymphoma: non-Hodgkin's lymphoma, the most prevalent form of lymphoma in Japan, is a diverse group of blood cancers that start in cells called lymphocytes, which are part of the body's immune system. Lymphocytes are found in the lymph nodes and other lymphoid tissues (such as the spleen and bone marrow). The disease is categorized by progression and is divided into low-grade (slow-growing) and intermediate to high-grade (fast-growing) types. Symptoms include swollen lymph nodes, weight loss, fever, and night sweats.

2 Multiple Myeloma: is a hematological cancer in which there is malignant proliferation of abnormal plasma cells that populate bone marrow in the body. The affected plasma cells produce myeloma protein, a monoclonal antibody that replaces normal antibodies in the blood, thereby increasing susceptibility to infection and renal failure. Symptoms include pain, anemia, weakness, bone fractures, and neurological symptoms.

About Bendamustine Hydrochloride (SyB L-0501)

Bendamustine was first synthesized in the early 1960s in 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 has received market authorization in a number of EU countries for bendamustine 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 in Japan (December, 2005), followed by signature of a second license agreement for the exclusive right to China/Hong Kong, Taiwan, South Korea and Singapore (March, 2007).

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/m^2 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.

About SymBio Pharmaceuticals Limited

SymBio Pharmaceuticals Ltd. was established in March, 2005, by Fuminori Yoshida, who previously served concurrently as Corporate VP of Amgen Inc. 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 with main focus in the areas of oncology, hematology and autoimmune disease.