SymBio Pharmaceuticals Limited

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

Completion of Patient Enrollment of TREAKISYM® (SyB L-0501) Phase II Trial in Frontline Low-grade Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma

TOKYO, Japan, March 6, 2013 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, "SymBio", JASDAQ: 4582) announced the completion of patient enrollment of its Phase II clinical trial of TREAKISYM® (bendamustine hydrochloride, SyB L-0501) in frontline low-grade non-Hodgkin's lymphoma (NHL)[1] and mantle cell lymphoma (MCL) patients in Japan. This randomized trial is evaluating the combination of TREAKISYM® and rituximab versus R-CHOP[2].

SymBio initiated this multicenter open-label Phase II trial as a line extension study for TREAKISYM® in November, 2011, in collaboration with Eisai. Completion of patient enrollment in this trial has occurred. "Thus far the study has progressed smoothly with no serious adverse events being reported," said Fuminori Yoshida, President and CEO of SymBio. Trial results with data analysis and evaluation will be finalized as soon as possible.

In partnership with Eisai Co., Ltd. (Eisai), SymBio received marketing approval of TREAKISYM® (SyB L-0501) in October, 2010, for the treatment of patients with relapsed/refractory low-grade NHL and MCL in Japan.

The number of low-grade non-Hodgkin's lymphoma patients in Japan is estimated to be approximately 11,000, including 4,000 refractory/relapsed patients and 7,000 untreated patients. Currently, R-CHOP is prescribed as a standard therapy, however, clinical trial results in the U.S. and Europe have shown superiority of the combination of rituximab and bendamustine (R-B) over R-CHOP in terms of safety and efficacy, leading to the inclusion of R-B in the National Comprehensive Cancer Network (NCCN) guidelines,[3] which are used by US physicians in prescribing oncology drugs.

SymBio has also initiated development of TREAKISYM® in refractory/relapsed intermediate and high-grade non-Hodgkin's lymphoma, and refractory/relapsed multiple myeloma. The Company also continues to pursue other indications in the hematology setting in order to maximize the potential of this 'pipeline within a molecule' and address other unmet medical needs.

[Please read the following to learn more about Bendamustine Hydrochloride (SyB L-0501) and SymBio Pharmaceuticals]

SymBio Pharmaceuticals Limited

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Note to Editors

Glossary

[1]Non-Hodgkin's lymphoma: is a diverse group of blood cancers that include any type of lymphoma, excluding Hodgkin's lymphomas, in which B or T white blood cells (lymphocytes) develop malignant growths. The disease is categorized by progression and is divided into low-grade (slow-growing) and intermediate to high-grade (fast-growing) types.

[2]R-CHOP: Combination therapy of Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisolone.

[3]Network (NCCN) guidelines: In alliance with 21 of the world's leading cancer centers, these guidelines are widely recognized and used as the standard for clinical treatment and policy in oncology by clinicians and payors.

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 by TEVA 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 a second license agreement for the exclusive regional rights to China/Hong Kong, Taiwan, South Korea and Singapore (March, 2007).

1. 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.

2. About SymBio Pharmaceuticals Limited

SymBio Pharmaceuticals Ltd, 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), aspires to be a leading commercial stage specialty pharmaceutical company in Asia Pacific dedicated to addressing underserved medical needs with main focus in the areas of oncology, hematology and autoimmune disease. The company's underlying corporate mission is "delivering hope to patients in need".