



May 8, 2013

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

Symbio Initiates Japanese Phase II Trial for TREAKISYM® (Bendamustine) in CLL

TOKYO, Japan, May 8, 2013 – Symbio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, “Symbio”, JASDAQ: 4582) announced today that it commenced enrollment in a Phase 2 clinical trial in Japan for bendamustine hydrochloride (Brand Name: TREAKISYM®) in chronic lymphocytic leukemia (CLL) patients.

In partnership with Eisai Co., Ltd., Symbio received marketing approval for TREAKISYM® (SyB L-0501) in October, 2010, to treat Japanese patients with relapsed/refractory (r/r) low-grade non-Hodgkin’s lymphoma (LG-NHL) and mantle cell lymphoma (MCL).

CLL is a cancer of the blood characterized by the progressive accumulation of functionally incompetent lymphocytes, a type of white blood cell produced by the bone marrow and organs of the lymphatic system. The number of CLL patients in Japan is estimated to be around 2,000. In the US and EU, bendamustine has been approved for the treatment of CLL where the disease accounts for an estimated 30% of all leukemia cases. Due to the lack of effective therapies in Japan, CLL patients are seriously underserved and a high unmet medical need exists for the development of an effective alternative therapy. In Japan, the Ministry of Health, Labour and Welfare (MHLW) Working Group has designated TREAKISYM® as a prioritized unapproved drug having high potential to address the lack of an effective therapy in CLL. TREAKISYM® was designated by MHLW as an orphan drug for the CLL indication in June, 2012.

Symbio has initiated several phase 2 trials for SyB L-0501. The Company continues to pursue other indications for TREAKISYM® in the hematology space as nimbly as possible in order to maximize the potential of TREAKISYM® and address other high unmet medical needs in patients.

[Please read the following for further information on TREAKISYM® and Symbio]

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About TREAKISYM® (SyB L-0501)

Bendamustine hydrochloride 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 has received marketing 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 originally acquired the exclusive right to develop and commercialize bendamustine in Japan (December, 2005) from Astellas Deutschland GmbH (Headquarters: Munich, Germany, formerly Astellas Pharma GmbH) followed by a second license agreement for the exclusive right to China, Hong Kong, Taiwan, South Korea and Singapore (March, 2007) where, China aside, the drug has been launched.

About TREAKISYM®

Product Name:

TREAKISYM® for Injection, for intravenous infusion 100 mg

Generic Name:

bendamustine hydrochloride

Indications and Usage:

For the treatment of relapsed/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 a repeated 21-day cycle. The dose may be reduced as deemed appropriate according to the patient's condition.

About Symbio Pharmaceuticals Limited

Symbio Pharmaceuticals 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 focus in oncology, hematology and autoimmune disease.