



June 14, 2012
Symbio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer

**SYMBIO ANNOUNCES ORPHAN DRUG DESIGNATION FOR TREAKISYM® (BENDAMUSTINE)
IN CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)**

TOKYO, Japan, June 14, 2012 – Symbio Pharmaceuticals Limited (JASDAQ: 4582) announced today that bendamustine hydrochloride (Brand Name: TREAKISYM®) has been designated as an orphan drug by the Ministry of Health, Labour, and Welfare (MHLW) for the treatment of chronic lymphocytic leukemia (CLL).

Drugs and biologics with orphan drug designation in Japan are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 50,000 patients (maximal incidence of four per ten thousand), with incentives for sponsors to develop orphan products such as priority review of New Drug Applications (NDAs) by the Pharmaceuticals and Medical Devices Agency (PMDA), 10 years of market exclusivity, and grant funding for sponsors.

CLL is a cancer of the blood characterized by a progressive accumulation of functionally incompetent lymphocytes, a type of white blood cell, produced by the bone marrow and by organs of the lymph system. The number of CLL patients in Japan is estimated to be around 2,000. In the U.S. 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 a lack of effective therapies in Japan, CLL patients are seriously underserved and the development of an effective alternative therapy is needed. In Japan, a Working Group of MHLW has designated TREAKISYM® as a prioritized unapproved drug having high potential for the treatment of unmet needs in CLL.

In partnership with Eisai Co., Ltd., Symbio received marketing approval of TREAKISYM® (SyB L-0501) in October, 2010, for the treatment of patients with relapsed/refractory (*r/r*) low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL) in Japan. A Phase II study for SyB L-0501 in *r/r* Aggressive NHL has been completed, with two Phase II studies in frontline low-grade NHL and MCL, and relapsed/refractory multiple myeloma patients currently underway.

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About Bendamustine Hydrochloride (SyB L-0501)

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 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 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).

About TREAKISYM®

Brand 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 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 Vice President 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 in oncology, hematology and autoimmune disease.