



January 7, 2013  
Symbio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer

Symbio Receives Clinical Trial Notification Acceptance for Phase 2  
TREAKISYM® (Bendamustine) Trial in CLL

TOKYO, Japan, January 7, 2013 – Symbio Pharmaceuticals Limited (JASDAQ: 4582) today announced that clinical trial notification (CTN) has been accepted for its phase 2 clinical trial in Japan using bendamustine hydrochloride (TREAKISYM®, SyB L-0501) for the treatment of patients with chronic lymphocytic leukemia (CLL). This CTN now allows Symbio to proceed with the clinical trial, which the Company expects to initiate shortly.

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 prevalence of CLL in Japan is estimated to be approximately 2,000 patients. Bendamustine has been approved for the treatment of CLL in the U.S. and EU, where the disease accounts for an estimated 30% of all leukemia cases. Due to the lack of effective therapies in Japan, CLL patients are severely underserved, representing a highly unmet medical need. In Japan, a Ministry of Health, Labour and Welfare (MHLW) Working Group has designated TREAKISYM® as a prioritized unapproved drug having high potential to address unmet medical needs in CLL.

In October, 2010, Symbio, along with its partner Eisai Co., Ltd., received marketing approval for TREAKISYM® for the treatment of Japanese patients with relapsed/refractory (r/r) low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL).

A phase 2 study for TREAKISYM® in r/r Aggressive NHL has been completed, with two phase 2 studies in frontline low-grade NHL and MCL, and relapsed/refractory multiple myeloma patients currently ongoing.

**[Please see 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 market authorization in a number of EU countries for bendamustine under the brand name "Levact®". In the United States, the drug 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).

## **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/m<sup>2</sup> 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 a focus in oncology, hematology and autoimmune disease.