

November 14, 2011  
Symbio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer

**Clinical Trial Notification Accepted for Symbio's Japan Phase 2 Trial  
of Bendamustine HCl (SyB L-0501) in Multiple Myeloma**

TOKYO, Japan, November 14, 2011 -- Symbio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, "Symbio") announced that clinical trial notification (CTN)<sup>1</sup> has been accepted for its phase 2 clinical trial using bendamustine hydrochloride (SyB L-0501) in refractory and relapsed multiple myeloma<sup>2</sup> (MM) patients.

In Japan, Symbio received marketing approval of TREAKISYM<sup>®</sup> (SyB L-0501) in October, 2010, for the treatment of patients with refractory/relapsed low-grade non-Hodgkin's lymphoma<sup>3</sup> and MM. Working with Eisai Co. Ltd., TREAKISYM<sup>®</sup> is expected to achieve rapid market penetration in Japan.

Regarding SyB L-0501 development in MM, Symbio has a second phase 2 clinical trial in frontline MM (untreated patients), but plans to prioritize development in refractory and relapsed MM (patients previously treated with other oncology drugs) due to the existence of higher unmet medical needs.

Symbio has also initiated phase 2 trials for SyB L-0501 in refractory/relapsed intermediate and high-grade non-Hodgkin's lymphoma, as well as in frontline low-grade non-Hodgkin's lymphoma patients. The Company continues to pursue other indications for TREAKISYM<sup>®</sup> in the hematology space as nimbly as possible in order to maximize the potential of this 'pipeline within a molecule' and address other unmet medical needs in patients.

Symbio's financial forecast for FY 2011 will not be revised due to the acceptance of clinical trial notification.

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

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<b>Note to Editors</b>
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## Glossary

**1 CTN:** Equivalent to the IND in US

**2 Multiple Myeloma:** is a hematological cancer in which there is malignant proliferation of abnormal plasma cells that populate the marrow-containing bones of 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. It is considered a progressive and incurable disease; the number of multiple myeloma patients in Japan is estimated to be around 13,000. The number of Refractory/relapsed and frontline patients will be almost same.

**3 Non-Hodgkin's lymphoma:** is cancer of the lymphoid tissue, which includes the lymph nodes, spleen, and other organs of the immune system, and is the most common form of lymphoma in Japan. Most lymphomas start in a type of white blood cells called B lymphocytes, or B cells. For most patients, the cause of this cancer is unknown, but lymphomas may develop in people with weakened immune systems. There are many different types of non-Hodgkin's lymphoma. It is classified according to how fast the cancer spreads. The cancer may be low grade (slow growing), intermediate grade, or high grade (fast growing). According to the American Cancer Society, a person has a 1 in 50 chance of developing non-Hodgkin's lymphoma. The number of low-grade non-Hodgkin's lymphoma<sup>1</sup> patients in Japan is estimated to be around 11,000, including 4,000 refractory/relapsed patients and 7,000 untreated patients.

## 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<sup>®</sup>" 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<sup>®</sup>." In the United States, the drug has been approved by the U.S. Food and Drug Administration and is marketed as TREANDA<sup>®</sup> 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).

### 1. About TREAKISYM<sup>®</sup>

**Product Name:**

TREAKISYM<sup>®</sup> 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<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.

## **2. About Symbio Pharmaceuticals Limited**

Symbio Pharmaceuticals Ltd. was 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 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 the areas of oncology, hematology and autoimmune disease.