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SymBio Pharmaceuticals Limited
Fuminori Yoshida
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# SymBio Announces Korea NDA Approval of Bendamustine Hydrochloride (SyB L-0501)

TOKYO, Japan, June 3, 2011 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, "SymBio") announced today that the Korea Food and Drug Administration (KFDA) in South Korea approved bendamustine HCI (SyB L-0501) for the treatment of patients with chronic lymphocytic leukemia and multiple myeloma on May 31, 2011. Eisai Korea Inc., the subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito), will promote the product.

In Japan, SymBio received market approval of TREAKISYM® (bendamustine) in October, 2010 for the treatment of patients with refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. Sales of TREAKISYM® in Japan are rapidly gaining momentum after launch in December, 2010. In other Asian markets, bendamustine has been approved in Hong Kong (December, 2009) and Singapore (January, 2010) for the treatment of patients with indolent non-Hodgkin's lymphoma and chronic lymphocytic leukemia. In addition to South Korea, bendamustine is also expected to receive market approval this year in Taiwan.

In its pursuit of aspiring to be a leading oncology specialty pharma in Asia Pacific, SymBio's business in key Asian markets continues to expand as it nimbly develops the use of bendamustine in the hematology space to address the unmet medical needs of patients.

**[Please see the following for further information on bendamustine hydrochloride and SymBio]**

**Note to Editors**

## 1. About Bendamustine Hydrochloride ("bendamustine")

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 several 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 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).

## 2. 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.

## 3. 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.

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