• SymBio
SymBio Pharmaceuticals Limited

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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director

President and Chief Executive Officer

SymBio Announces Korea NDA Approval of Additional Indication for Bendamustine

Hydrochloride (SyB L-0501)

TOKYO, Japan, June 18, 2014 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio")

announced that the Ministry of Food and Drug Safety (MFDS) in South Korea approved bendamustine HCI

(SyB L-0501) for the treatment of patients with relapsed or refractory low-grade non-Hodgkin's lymphoma on

June 16, 2014. Bendamustine was earlier approved by the formerly known Korea Food and Drug

Administration (KFDA) in South Korea for the treatment of chronic lymphocytic leukemia and multiple

myeloma in on May 31, 2011. Eisai Korea Inc., a subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President

& CEO: Haruo Naito), promotes the products.

In Japan, SymBio received market approval of TREAKISYM® (Bendamustine) in October, 2010 for the

treatment of patients with refractory or relapsed low grade non-Hodgkin's lymphoma and mantle cell lymphoma. In other Asian markets, Bendamustine has been approved in Hong Kong (December, 2009),

Singapore (January, 2010) and Taiwan (October, 2011) for the treatment of patients with low-grade

non-Hodgkin's lymphoma and chronic lymphocytic leukemia.

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 and commercializes Bendamustine (SyB L-0501) in the

hematology space to address the underserved medical needs of patients.

[Please read the following to learn more about Bendamustine Hydrochloride (SyB L-0501) and

SymBio Pharmaceuticals]

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Note to Editors

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 "Levact®" 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 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).

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. 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 main focus in the areas of oncology, hematology and autoimmune disease.