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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer

Completion of Patient Enrollment of TREAKISYM® Phase II Trial in Patient with Chronic Lymphocytic Leukemia (CLL)

TOKYO, Japan, November 5, 2014 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced the completion of patient enrollment of Phase II clinical trial in Japan for TREAKISYM® (bendamustine hydrochloride, SyB L-0501) in patients with chronic lymphocytic leukemia (CLL).

In partnership with Eisai Co., Ltd., SymBio received marketing approval for TREAKISYM® (SyB L-0501) in October, 2010, to treat Japanese patients with relapsed/refractory (r/r) low-grade non-Hodgkin's lymphoma (LG-NHL) and mantle cell lymphoma (MCL).

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 number of CLL patients in Japan is estimated to be around 2,000. In the US 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 the lack of effective therapies in Japan, CLL patients are seriously underserved and a high unmet medical need exists for the development of an effective alternative therapy. In Japan, the Ministry of Health, Labour and Welfare (MHLW) Working Group has designated TREAKISYM® as a prioritized unapproved drug having high potential to address the lack of an effective therapy in CLL. TREAKISYM® was designated by MHLW as an orphan drug for the CLL indication in June, 2012.

The Company continues to nimbly pursue other TREAKISYM® indications for development and commercialization in Japan and other key Asia Pacific markets, thereby maximizing the drug's potential as it addresses the high unmet medical needs of patients.



[Please read the following for more information on Non-Hodgkin's lymphoma, Bendamustine and SymBio]

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[Glossary]

About Non-Hodgkin's lymphoma

Non-Hodgkin's lymphoma is a diverse group of blood cancers that include various types of lymphoma, excluding Hodgkin's lymphomas, in which B or T white blood cells (lymphocytes) develop malignant growths. The disease is categorized by progression and is divided into low-grade (slow-growing) and intermediate to high-grade (fast-growing) disease. In addition, the number of low-grade non-Hodgkin's lymphoma patients in Japan is estimated to be approximately 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®" 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 by TEVA 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 exclusive regional rights 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.