

October 19, 2015
Symbio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President & Chief Executive Officer

Completion of TREAKISYM® Phase II Trial in Chronic Lymphocytic Leukemia

TOKYO, Japan, October 19, 2015 --- Symbio Pharmaceuticals limited (Headquarters: Tokyo, “Symbio”) announced today the completion of its Phase II clinical trial in Japan for TREAKISYM® (bendamustine hydrochloride, SyB L-0501) in patients with chronic lymphocytic leukemia (CLL).

Bendamustine has been approved for the treatment of CLL in Europe and the United States.

In Japan, TREAKISYM® was designated by the Ministry of Health, Labour and Welfare (MHLW) as an orphan drug for the CLL indication in June, 2012, and the "Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs," a committee established by the MHLW, has designated TREAKISYM® as a prioritized unapproved drug having high potential to address the lack of effective therapies in CLL.

Symbio plans to submit an application for approval of the CLL indication in Japan in 1Q 2016 using data from Phase III clinical trials conducted in Europe and the United States.

Completion of the Phase II trial in CLL will not impact the Company’s financial forecast for FY2015.

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About Bendamustine Hydrochloride (TREAKISYM®)

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).

About chronic lymphocytic leukemia (CLL)

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.

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 to "deliver 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 therapeutic focus in oncology, hematology and autoimmune disease.