



Symbio Pharmaceuticals Limited  
San-Ei Building, 5-23-7 Shimbashi, Minato-ku, Tokyo 105-0004, Japan  
Tel: +81-3-5472-1125 Fax: +81-3-5472-3054 <http://www.symbiopharma.com/>

October 30, 2009

Symbio Pharmaceuticals Limited.

Fuminori Yoshida

Representative Director  
President and Chief Executive Officer

## **Symbio Announces NDA Submission for SyB L-0501 (bendamustine hydrochloride)**

TOKYO, Japan, October 30, 2009 -- Symbio Pharmaceuticals Limited (Headquarters: Tokyo, "Symbio,") announced today that on October 30, the Company submitted its New Drug Application (NDA) to the Pharmaceuticals and Medical Devices Agency (PMDA) for SyB L-0501 (bendamustine hydrochloride) for the treatment of refractory and relapsed low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma.

On October 28, Symbio received official notification from the Ministry of Health, Labour and Welfare (MHLW) granting SyB L-0501 orphan drug designation for both aforementioned indications, and as a result, the drug will undergo a priority review process upon NDA filing in Japan. The results of the phase III clinical trial against first-line therapy being conducted in Germany will be presented at the 51st ASH Annual Meeting and Exposition to be held in New Orleans this December 5-8, 2009.

"I am very pleased that this first NDA, representing the achievement of a major milestone and culmination of our efforts, has been filed in only four and half years since our company's inception," commented Mr. Fuminori Yoshida, President and CEO of Symbio. "Filing the first NDA in such a short period of time clearly demonstrates the effectiveness of the organization we have in place at Symbio, as well as the capital efficiency of our business model – essentially a validation of our business model. We are now in high gear towards delivering this important therapeutic to NHL patients in Japan and other regions of Asia Pacific."

### **[SyB L-0501]**

Symbio holds exclusive rights to SyB L-0501, the Company's first drug candidate, from Astellas Deutschland GmbH for development and commercialization in Japan, China (HK), Taiwan, Korea and Singapore, and is actively building partnerships through the execution of license agreements with quality companies in each country in order to bring bendamustine hydrochloride to Asian markets as expeditiously as possible. The drug is already listed in the NCCN (National Comprehensive Cancer Network) Clinical Practice Guidelines in Oncology, the recognized standard for clinical policy in oncology.

[Company Profile]

SymBio Pharmaceuticals Ltd. was established in March, 2005 by Fuminori Yoshida, who previously served as both Corporate VP of Amgen Ltd. and President of Amgen Japan (currently Takeda Bio Development Center Limited). The company's underlying corporate mission is "delivering hope to patients in need", aspiring to be a leading specialty pharmaceutical company in the Asia Pacific Rim dedicated to addressing underserved medical needs in the areas of oncology, hematology and autoimmune disease.

[Contact]

SymBio Pharmaceuticals Limited.

Hiroki Maekawa

Corporate Officer

Head of Corporate Division

Tel: +081(0)3 5472 1125

e-mail: Please send your inquiry through "INQUIRY" in our homepage

URL: <http://www.symbiopharma.com>