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SymBio Pharmaceuticals Limited
Fuminori Yoshida
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SYMBIO ANNOUNCES RESULTS PRESENTED AT ASCO 2012 EVALUATING CLINICAL BENEFITS OF TREAKISYM® (BENDAMUSTINE) IN COMBINATION WITH RITUXIMAB IN PATIENTS WITH RELAPSED/REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL)

Multicenter Phase II study reports ORR of 63% with a 37% CR rate; median PFS of 6.7 months

TOKYO, Japan, June 1, 2012 – SymBio Pharmaceuticals Limited (JASDAQ: 4582) announced today that results from a multicenter, Phase II study assessing the efficacy and safety of bendamustine in combination with rituximab (B-R) in patients with relapsed/refractory DLBCL were presented at the 2012 American Society of Clinical Oncology Annual Meeting (ASCO) in Chicago, IL. Results of this study, conducted by the Japanese and Korean Bendamustine/Lymphoma Study Group, were presented by Dr. Michinori Ogura (Nagoya Daini Red Cross Hospital) during the Lymphoma and Plasma Cell Disorders poster discussion session on Saturday, June 2, 2012. This study showed that B-R chemoimmunotherapy had promising efficacy and safety in patients with relapsed/refractory DLBCL. The data also suggests that B-R therapy may be equally efficacious between elderly and younger patients with relapsed/refractory DLBCL as there were no major differences in objective tumor response rates.

In the study, patients with relapsed/refractory DLBCL who had failed prior therapies were administered rituximab (375 mg/m^2 IV) on day 1 and bendamustine (120 mg/m^2 IV) for at least 60 minutes on days 2 and 3 of each 21-day cycle, for up to 6 cycles. A total of 63 patients were enrolled in the study, and data from 59 patients were available.

The primary endpoint of the study was overall response rate (ORR), measured according to the Revised Response Criteria for Malignant Lymphoma (Revised RC; Journal of Clinical Oncology, 2007). Secondary endpoints included complete response (CR) rate, progression-free survival (PFS), and safety. The ORR in 59 evaluable patients was 62.7% [95% Confidence Interval (CI): 49.1%-75.0%] with a 37.3% CR rate [95% CI: 25.0%-50.9%]. There was no meaningful difference in tumor response rates between the elderly [age≥65 years; 63.6% ORR] and younger [age <65 years; 62.2% ORR] patients. The median PFS of all 59 patients was 6.7 months [95% CI: 3.6-13.7 months].

Toxicities in the study were primarily hematologic in nature and generally manageable. The major hematologic toxicities of grade 3 or 4 were CD4+ lymphopenia (66.1%), leukopenia (55.9%), lymphopenia (55.9%), and neutropenia (54.2%). No grade 4 non-hematologic toxicity was observed. These results suggest that B-R is a promising salvage regimen for patients with relapsed/refractory DLBCL after R-CHOP.

Due to the lack of effective therapies, relapsed/refractory aggressive NHL patients over 70 years old are seriously undeserved and an effective new therapy needs to be developed in light of the rapidly aging population in Japan.

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About Bendamustine Hydrochloride (SyB L-0501)

Bendamustine was first synthesized in the early 1960s in the 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 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 to develop and commercialize bendamustine in Japan (December, 2005) from Astellas Deutschland GmbH (Headquarters: Munich, Germany, formerly Astellas Pharma GmbH) followed by a second license agreement for the exclusive right to China, Hong Kong, Taiwan, South Korea and Singapore (March, 2007).
For Japan, in partnership with Eisai Co., Ltd., SymBio received marketing approval of TREAKISYM® (SyB L-0501) in October, 2010, for the treatment of patients with relapsed/refractory low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL). SymBio has also initiated Phase II trials for SyB L-0501 in frontline low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL), and relapsed/refractory multiple myeloma patients.

About TREAKISYM®
Product Name:
TREAKISYM® for Injection, for intravenous infusion 100 mg

Generic Name:
bendamustine hydrochloride

Indications and Usage:
For the treatment of relapsed/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/m2 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.

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 (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 oncology, hematology and autoimmune disease.