SymBio Pharmaceuticals Limited

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SymBio Pharmaceuticals Limited
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Representative Director
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SymBio Announces Development Status of TREAKISYM® in Refractory and Relapsed Aggressive Non-Hodgkin's Lymphoma

TOKYO, Japan, May 30, 2012 – SymBio Pharmaceuticals Limited (JASDAQ: 4582) announced today that during the Company's pre-NDA meeting with the Japan Pharmaceuticals and Medical Devices Agency (PMDA), the agency indicated that it requires further clinical data for supplemental NDA submission of bendamustine hydrochloride (Product Name: TREAKISYM®) for the treatment of refractory and relapsed (r/r) aggressive non-Hodgkin's lymphoma (NHL). Based on the PMDA's comments, SymBio does not anticipate the submission of an NDA this year and will continue to consult with key investigators in the lymphoma field to explore all available options to meet supplemental NDA filing requirements in Japan, especially given the lack of effective alternative therapies for elderly r/r aggressive NHL patients who are unable to undergo autologous stem cell transplantation.

SymBio initially planned to file the supplemental NDA based on positive results from its Phase 2 international collaborative study of TREAKISYM in combination with rituximab (R) for the treatment of r/r aggressive NHL. Data from this study demonstrated the TREAKISYM-R combination regimen to be highly efficacious with a 62.7% overall response rate, 37.3% complete response rate, and 200-day median progression-free survival. Toxicity was primarily hematologic in nature and generally manageable for patients in the trial, including the elderly. The results of this Phase 2 trial will be presented at the American Society of Clinical Oncology (ASCO) meeting in Chicago on June 2, 2012, by Dr. Ogura (Nagoya, Daini Red Cross Hospital).

SymBio is working closely with its development and commercial partner, Eisai Co., Ltd., as its future development strategy for TREAKISYM® continues to evolve. TREAKISYM® is currently on the market in Japan for the treatment of r/r low-grade NHL and mantle cell lymphoma, and has been launched in Singapore, Hong Kong, Korea and Taiwan. First-year 2011 sales of TREAKISYM® were US $41 million. SymBio's financial forecast for FY2012 remains unchanged, and any impact that this development change may have on the Company's long range forecast will be disclosed after further review of clinical strategies for TREAKISYM®.

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Glossary

1 non-Hodgkin's lymphoma: is a diverse group of blood cancers that include any type 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) types. 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.

2 Overall Response Rate: is the sum of complete and partial tumor responses observed in a study, divided by the number of evaluable patients.

3 Complete Response Rate: is the sum of complete tumor responses, divided by the number of evaluable patients. Complete tumor response means the disappearance of all signs of cancer in response to treatment, but does not necessarily mean that a particular cancer has been cured.

4 Progression Free Survival: is the length of time a patient remains alive and free of any significant increase in his/her disease.

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 rights to China, Hong Kong, Taiwan, South Korea and Singapore (March, 2007).

In Japan, SymBio received marketing approval of TREAKISYM® (SyB L-0501) in October, 2010, for the treatment of patients with refractory/relapsed low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL). Working with Eisai Co., Ltd., TREAKISYM® is expected to achieve rapid market penetration
in Japan.SymBio has also initiated phase 2 trials for SyB L-0501 in frontline low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL) and also refractory/relapsed 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 or 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 Ltd. 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.