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SymBio Pharmaceuticals Limited
Eisai Co., Ltd.

SYMBIO AND EISAI ANNOUNCE REMOVAL OF TREAKISYM® INJECTION 100 MG ALL CASES SURVEILLANCE CONDITION FOR JAPAN MARKETING APPROVAL

SymBio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, "SymBio") and Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that they have received notification from the Japanese Ministry of Health, Labour and Welfare (MHLW) informing the companies that the condition for TREAKISYM® (bendamustine hydrochloride) marketing approval, *All Cases Surveillance*,[*1] has been lifted in Japan.

In October 2010, SymBio received marketing approval from the MHLW for TREAKISYM® to treat Japanese patients with relapsed/refractory low-grade non-Hodgkin's lymphoma*[2] (LG-NHL) and mantle cell lymphoma (MCL), and the agent has been marketed by Eisai in Japan since its launch in December 2010, based on an ongoing license agreement between SymBio and Eisai. The original condition for approval by the MHLW stated that due to the very limited number of subjects treated in domestic clinical trials, post-marketing surveillance of all patients who receive TREAKISYM® should be carried out until data for a certain number of patients has been collected in order to identify patient background as well as early safety and efficacy data, and necessary measures for the proper use of TREAKISYM®.

Safety data for 583 patients, and efficacy data for 497 patients, was submitted to the MHLW as an analysis of data collected during post-marketing surveillance*[3]. Based on this analysis, MHLW concluded that post-marketing surveillance had been conducted properly with necessary measures for proper use of the drug in place, and accordingly, no further surveillance is required.

As part of the life cycle management of the agent, the development of TREAKISYM® for other indications is underway in Japan, including a Phase 2 study in primary LG-NHL and MCL. Both companies will work closely together in an effort to meet unmet medical needs and continue to expedite development of TREAKISYM so as to provide the drug as early as possible to patients who need it.

[Please read the following for further information on terms *[1] to *[3], TREAKISYM® (Bendamustine hydrochloride) including a product outline, and corporate profile of SymBio and Eisai]

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[Notes to Editors]

1. About the *All Cases Surveillance*

The *All Cases Surveillance* collected data on use results concerning the safety and efficacy of TREAKISYM® in patients with relapsed/refractory low-grade non-Hodgkin's lymphoma or mantle cell lymphoma in Japan. The data was collected in order to understand the following objectives:

(1) Expression of side effects
(2) Factors thought to influence safety, efficacy, and related issues
(3) Other major points of focus of the surveillance (severe infection, tumor lysis syndrome, severe skin disorders, and expression of hypersensitivity reactions)

2. About Non-Hodgkin's Lymphoma (NHL)

Non-Hodgkin's lymphomas (NHLs) are a diverse group of blood cancers that include any kind of lymphoma, which is a kind of white blood cell, with the exception of Hodgkin's lymphomas, and comprises the majority of lymphoma cases in Japan. NHLs are often classified into two groups based on their progression rate: slow-growing NHLs whose progression is measured in years are classified as low-grade (LG), while those whose progression is measured in months are classified as intermediate- or high-grade (Aggressive) NHLs. There are an estimated 11,000 patients with LG-NHL in Japan. Of this number, 4,000 are believed to be patients with relapsed/refractory LG-NHL and 7,000 to be patients with primary LG-NHL.

3. About the Analysis of the *All Cases Surveillance*

According to the results of the analysis, side effects were reported in 564 cases out of a total of 583 cases analyzed in terms of patient safety, with the incidence rate at 96.74%. The main side effects were lymphopenia at 71.87%, leukopenia at 57.46%, neutropenia at 55.57%, thrombocytopenia at 40.14%, anemia at 19.55%, and nausea at 19.21%. These side effects were consistent with outcomes reported for clinical trials carried out overseas to date as well as trials conducted in Japan at the time of development.

4. About TREAKISYM® (Bendamustine hydrochloride)

Bendamustine hydrochloride was first synthesized in the former East Germany by Jenapharm and is currently marketed in Europe under the brand name Ribomustin® or Levact® as a treatment for non-Hodgkin's lymphoma, multiple myeloma and chronic lymphocytic leukemia. In the United States, the drug is marketed as TREANDA® for the treatment of chronic lymphocytic leukemia and relapsed/refractory B-cell non-Hodgkin's lymphoma.

In December 2005, SymBio Pharmaceuticals acquired the exclusive right to develop and commercialize the agent, as its first developmental drug, in Japan, China including Hong Kong, Taiwan, South Korea and Singapore from Astellas Deutschland GmbH. Based on a sublicensing agreement with SymBio, Eisai acquired co-development and exclusive marketing rights in Japan and exclusive development and marketing rights in South Korea and Singapore in May 2009. SymBio granted exclusive development and marketing rights in China including Hong Kong based on a licensing agreement with Cephalon, Inc. (currently Teva Pharmaceutical Industries Ltd.) in March 2009. (The development and marketing rights for bendamustine hydrochloride are held by Teva Pharmaceutical Industries Ltd. in North America, Mundipharma International Ltd. in Europe, and Janssen-Cilag Ltd. in other regions.)

5. About TREAKISYM® Product Outline

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/m^2 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.

6. 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 with a focus in oncology, hematology and autoimmune disease.

7. About Eisai Co., Ltd.

Eisai Co., Ltd. is a research-based pharmaceutical company that discovers, develops and markets products worldwide. Guided by its corporate mission of "giving first thought to patients and their families, and to increasing the benefits that healthcare provides," all Eisai employees aspire to meet the various needs of global healthcare as representatives of a "*human health care* (*hhc*) company" that is capable of making a meaningful contribution under any healthcare system. For more information about Eisai Co., Ltd., please visit www.eisai.com.