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Eisai Co., Ltd.

ANTICANCER AGENT "TREAKISYM® FOR INJECTION 100 MG" APPROVED IN JAPAN FOR ADDITIONAL INDICATION OF CHRONIC LYMPHOCYTIC LEUKEMIA

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the anticancer agent TREAKISYM® for Injection 100 mg (generic name: bendamustine hydrochloride, "TREAKISYM") has been approved in Japan for an additional indication of chronic lymphocytic leukemia. TREAKISYM is the subject of a licensing agreement concluded between Eisai and SymBio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, "SymBio").

TREAKISYM was initially approved in Japan in October 2010 for relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma. Under the licensing agreement concluded between the two companies, Eisai has been marketing the product in Japan since its launch in December 2010.

Symbio filed an application for this additional indication in December 2015 in response to a development request from the Japanese Ministry of Health, Labour and Welfare's Study Group on Unapproved and Off Label Drugs with high unmet medical needs. Chronic lymphocytic leukemia is a blood cancer characterized by neoplastic transformation and excess propagation of lymphocytes, a type of white blood cell, in the bone marrow. With approximately 2,000 patients with chronic lymphocytic leukemia in Japan as well as an incidence rate of new cases of approximately 0.3 in 100,000, this is a disease with high unmet medical need. Furthermore, TREAKISYM has been designated as an orphan drug for chronic lymphocytic leukemia in Japan.

Eisai positions oncology as a key therapeutic area and is aiming to discovery revolutionary new medicines with the potential to cure cancer. Eisai remains committed to maximizing the value of TREAKISYM as well as its in-house developed anticancer agents including Halaven® and Lenvima®, seeking to contribute further to addressing the diverse needs of patients with cancer and their families.

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[Notes to editors]

1. About bendamustine hydrochloride (generic name, product name: TREAKISYM)

Bendamustine hydrochloride is an anticancer agent originally synthesized by German (formerly 'East German') pharmaceutical company Jenapharm and is marketed in Europe under the brand names Ribomustin® and Levact® as a treatment for non-Hodgkin's lymphoma, multiple myeloma and chronic lymphocytic leukemia. In the United States the product has been approved by the U.S. Food and Drug Administration and is currently marketed under the brand name TREANDA® for the treatment of chronic lymphocytic leukemia and relapsed indolent B-cell non-Hodgkin's lymphoma. Eisai concluded an exclusive licensing agreement with SymBio in August 2008 concerning the joint development and marketing of TREAKISYM in Japan, which was followed by a subsequent agreement between the two companies in May 2009 concerning the development and marketing of the agent in Singapore and South Korea.

2. About TREAKISYM (additional parts have been underlined)

Product Name:

TREAKISYM® for Injection, for intravenous infusion 100 mg

Generic Name:

Bendamustine Hydrochloride

Indications and Usage:

1. For the treatment of relapsed or refractory forms of the following diseases:
   Low-grade B-cell non-Hodgkin's lymphoma
   Mantle cell lymphoma
2. Chronic lymphocytic leukemia

Dosage and Administration:

1. For relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma or mantle cell lymphoma
   The usual adult dose of bendamustine hydrochloride is 120 mg/m^2 body surface area infused intravenously over 60 minutes on Days 1 and 2 of repeated 21-day cycles. The dose may be reduced appropriately according to the patient's condition.
2. For chronic lymphocytic leukemia
   The usual adult dose of bendamustine hydrochloride is 100 mg/m^2 body surface area infused intravenously over 60 minutes on Days 1 and 2 of repeated 28-day cycles. The dose may be reduced appropriately according to the patient's condition.