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Eisai Co., Ltd.

ANTICANCER AGENT TREAKISYM® APPROVED IN JAPAN FOR ADDITIONAL INDICATION AS FIRST-LINE TREATMENT FOR LOW-GRADE B-CELL NON-HODGKIN'S LYMPHOMA AND MANTLE CELL LYMPHOMA

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the anticancer agent TREAKISYM® (generic name: bendamustine hydrochloride) has been approved in Japan for an additional indication as first-line treatment for low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma (MCL). TREAKISYM is the subject of a licensing agreement concluded between Eisai and SymBio Pharmaceuticals Limited (Headquarters: Tokyo, Representative Director, President & CEO: Fuminori Yoshida, "SymBio"). Through the approval of this additional indication, TREAKISYM will now be available for adjunctive use with rituximab for untreated low-grade B-cell non-Hodgkin's lymphoma and MCL.

TREAKISYM was initially approved in Japan in October 2010 as monotherapy for relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma and MCL. Under the licensing agreement concluded between the two companies, Eisai has been marketing the product since December 2010. In August 2016, TREAKISYM was approved in Japan for an additional indication of chronic lymphocytic leukemia. For this approval of the indication for first-line low-grade B-cell non-Hodgkin's lymphoma and MCL, this indication met the development requests set by the Japanese Ministry of Health, Labour and Welfare's Council on Unapproved Drugs/Off-label Use, and SymBio submitted a supplemental New Drug Application in December 2015.

Non-Hodgkin's lymphoma is a general term that refers to lymphocytes within white blood cells that have mutated into lymphomas, except for Hodgkin's lymphoma, and represent the majority of lymphomas diagnosed in Japan. Non-Hodgkin's lymphoma is categorized by progression speed, which means lymphoma progressing annually is low-grade, monthly is mid-grade and weekly is high-grade. In addition, non-Hodgkin's lymphoma can be further categorized by which cells have become cancerous (such as B-cells) and how mature the cells are. As low-grade B-cell non-Hodgkin's lymphoma and MCL are difficult to cure completely, they are both diseases with high unmet medical needs.

Eisai positions oncology as a key therapeutic area and is aiming to discover 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 for injection 25 mg, 100 mg)

Bendamustine hydrochloride is an anticancer agent originally synthesized by German (formerly 'East German') pharmaceutical company Jenapharm and is marketed in Europe as a treatment for diseases such as non-Hodgkin's lymphoma, multiple myeloma and chronic lymphocytic leukemia. In the United States the product is currently marketed for the treatment of chronic lymphocytic leukemia and relapsed 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 (changed parts have been underlined)

Product Name:

TREAKISYM® for Injection, for intravenous infusion 25 mg, 100 mg

Generic Name:

bendamustine hydrochloride

Indications and Usage:

1. Low-grade B-cell non-Hodgkin's lymphoma
   Mantle cell lymphoma
2. Chronic lymphocytic leukemia

Dosage and Administration:

1. For low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma
   (1) As first-line treatment
   When used adjunctively with rituximab (recombinant DNA), the usual adult dose of bendamustine hydrochloride is 90 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.
   (2) For relapsed or refractory disease
   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.