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Eisai Co., Ltd.

EISAI ANNOUNCES JAPAN APPROVAL OF ANTICANCER AGENT TREAKISYM[®]

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the anticancer agent TREAKISYM[®] (generic name: bendamustine hydrochloride) has received marketing approval in Japan for the treatment of relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma. TREAKISYM[®] is the subject of a licensing agreement concluded between Eisai and SymBio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, "SymBio"). Under the terms of the agreement, SymBio is responsible for developing and obtaining marketing approval for the drug in Japan, while Eisai will market it exclusively. TREAKISYM[®] will be the first anticancer for Eisai to launch in Japan.

TREAKISYM[®] is a novel anticancer agent that exhibits both nitrogen mustard-derived alkylating activity and antimetabolic-like activity. Clinical studies conducted in Japan showed that TREAKISYM[®] offers excellent efficacy, has a high response rate, and significantly extends the duration of progression-free survival. More importantly, it is the first single agent for which patients with mantle cell lymphoma demonstrated a complete response. While the most frequently reported adverse reactions associated with TREAKISYM[®] include myelosuppression, nausea, vomiting, infection, vasculitis and angialgia, the agent maintains a manageable and tolerable safety profile.

Eisai concluded an exclusive licensing agreement with SymBio in August 2008 concerning the joint development and marketing of bendamustine hydrochloride 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. Bendamustine hydrochloride has been marketed in Singapore by Eisai's Singapore subsidiary Eisai (Singapore) Pte. Ltd under the brand name Symbenda[®] since September 2010. In Japan, SymBio is currently conducting Phase II clinical studies with the agent for intermediate- and high-grade non-Hodgkin's lymphoma and untreated multiple myeloma as part of an indication expansion program.

Eisai positions oncology as a therapeutic area of focus. Following the debut of its first anticancer agent TREAKISYM[®], Eisai plans to continue to expand its portfolio of oncology products with agents such as eribulin (generic name), the company's first in-house developed anticancer agent currently under regulatory review for the treatment of breast cancer, thereby making further contributions to addressing the diversified needs of cancer patients and their families.

**[Please refer to the following notes for further information on
bendamustine hydrochloride and the approved product]**

Media Inquiries:

Public Relations Department,

Eisai Co., Ltd.

+81-(0)3-3817-5120

[Notes to editors]

1. About Bendamustine Hydrochloride

Bendamustine hydrochloride is an anticancer agent originally synthesized by German (formerly 'East German') pharmaceutical company Jenapharm and is marketed in Germany 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 prescribed under the brand name TREANDA[®] for the treatment of chronic lymphocytic leukemia and relapsed indolent B-cell non-Hodgkin's lymphoma.

SymBio Pharmaceuticals Limited acquired the exclusive rights to develop and market bendamustine hydrochloride in Japan, China, South Korea, Taiwan and Singapore from Astellas Deutschland GmbH (Headquarters: Munich, Germany, formerly Astellas Pharma GmbH).

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[®]

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 diseases:

- Low-grade B-cell non-Hodgkin's lymphoma
- Mantle cell lymphoma

Dosage and Administration:

- The usual 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 appropriately according to the patient's condition.