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Eisai Co., Ltd.

PHASE III TRIAL OF ANTICANCER AGENT HALAVEN® IN SOFT TISSUE SARCOMA SHOWS OVERALL SURVIVAL BENEFIT IN PRIMARY ENDPOINT

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that in a Phase III clinical trial (Study 309) of its in-house discovered and developed anticancer agent eribulin mesylate ("eribulin," Brand name: Halaven®) in patients with soft tissue sarcomas, eribulin demonstrated a statistically significant extension in overall survival (OS) over the comparator treatment dacarbazine, and the study met its primary endpoint. No other systemic treatment for locally advanced or metastatic soft tissue sarcoma has been reported to extend overall survival in a Phase III study. Eribulin, as a single agent, has now demonstrated overall survival benefit in two distinct solid tumor types (metastatic breast cancer and soft tissue sarcomas), following two prior regimens in the advanced setting.

Study 309 was a randomized, open-label, multicenter, Phase III study comparing the efficacy and safety of eribulin versus dacarbazine in 452 patients (aged 18 or over) with locally advanced or recurrent and metastatic soft tissue sarcoma (one of two subtypes: adipocytic or leiomyosarcoma) who have disease progression following standard therapies which must have included an anthracycline and at least one other additional regimen. The primary endpoint of the study was to compare OS between both treatment arms. In this study, the most common adverse events observed in the eribulin arm were neutropenia, fatigue, nausea, alopecia, and constipation, which was consistent with the known side-effect profile of eribulin. Detailed results of the study will be presented at an academic conference in the near future.

Based on the results of Study 309, Eisai intends to submit applications during the first half fiscal 2015 to the regulatory authorities in multiple countries including Japan, the United States and Europe seeking an expansion of the indication for eribulin to include soft tissue sarcoma.

Soft tissue sarcoma is a rare form of malignant tumor with approximately 2,000 cases in Japan and approximately 12,000 cases in the United States diagnosed each year. In Europe, soft tissue sarcoma affects an estimated 4 to 5 out of every 100,000 people. While treatment of soft tissue sarcoma is focused on curative surgery, if the degree of malignancy is high, treatment then becomes a combination of chemotherapy and radiation therapy. As outcomes are poor for patients with advanced disease, it remains a disease with highly significant unmet medical needs. The study results have shown that eribulin has the potential to be an efficacious new treatment in this aggressive and complex cancer. Eribulin has been designated as an orphan drug for the treatment of soft tissue sarcoma in the United States and Japan.

First in the halichondrin class, Halaven is a microtubule dynamics inhibitor with a novel mechanism of action. It was first approved for the treatment of metastatic breast cancer in the United States in November 2010, and is currently approved in nearly 60 countries including Japan and countries in Europe, the Americas and Asia.

Eisai remains committed to providing further clinical evidence for eribulin aimed at maximizing value of the

drug as it seeks to contribute further to addressing the diverse needs of, and increasing the benefits provided to, patients with cancer, their families, and healthcare providers.

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[Notes to editors]

1. About Halaven (eribulin mesylate)

Halaven, a halichondrin class microtubule dynamics inhibitor with a novel mechanism of action, belongs to a class of antineoplastic agents, the halichondrins, which are natural products isolated from the marine sponge *Halichondria okadai*. It is believed to work by inhibiting the growth phase of microtubule dynamics without affecting the shortening phase and sequestering tubulin into nonproductive aggregates.

Halaven was first approved as a treatment for breast cancer in the United States in November 2010, and is now approved in nearly 60 countries worldwide, including Japan and countries in the Americas, Europe and Asia. In Japan, Halaven has been approved to treat inoperable or recurrent breast cancer and was launched in the country in July 2011. Since June 2014, Eisai has been obtaining approval in countries in Europe and Asia for the indication expansion of Halaven to contribute earlier treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting, unless patients were not suitable for these treatments. In addition, Halaven has been designated as an orphan drug for soft-tissue sarcoma in the United States and Japan.

2. About Soft Tissue Sarcoma

Soft tissue sarcoma is a collective term for a diverse group of malignant tumors that occur throughout the soft tissue in the body. As the structures where the tumors originate are diverse, there are an extremely large number of types of sarcoma, and the most common types include leiomyosarcoma, adipocytic and malignant fibrous histiocytoma. It is a rare form of cancer with a global incidence rate of 2 or 3 out of every 100,000 people. While treatment of soft tissue sarcoma is focused on curative surgery, if the degree of malignancy is high, treatment then becomes a combination of chemotherapy and radiation therapy. As outcomes are poor for patients with advanced disease, it remains a disease with highly significant unmet medical needs.