EISAI FILES FOR INDICATION EXPANSION OF ANTICANCER AGENT HALAVEN® WITH EUROPEAN MEDICINES AGENCY

SEEKS EARLIER-LINE USE IN TREATMENT OF METASTATIC BREAST CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that its U.K. subsidiary, Eisai Europe Ltd., has filed an application with the European Medicines Agency (EMA) for anticancer agent Halaven® (eribulin mesylate, “eribulin”), requesting an indication expansion of eribulin to contribute to earlier-line treatment of patients with metastatic breast cancer.

Among the clinical evidence submitted with the application were results of a multicenter, randomized, open-label, Phase III clinical study (Study 301) that compared eribulin versus capecitabine in 1,102 patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane. The majority of the patients received zero or one previous chemotherapeutic regimens for metastatic disease.

Also provided as clinical evidence was the outcome of a Phase III clinical study (Study 305: EMBRACE) of eribulin versus treatment of physician’s choice (TPC) in patients with locally advanced or metastatic breast cancer who had previously received two to five chemotherapeutic regimens. The study results demonstrate eribulin to be the first and only single-agent chemotherapy in the world to statistically, significantly extend overall survival

[Notes to editors]

1. About Halaven® (eribulin mesylate)

Halaven, a non-taxane, 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.

In a Phase III clinical study (EMBRACE) conducted overseas of Halaven versus treatment of physician's choice (TPC) in 762 patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane, Halaven indicated extended overall survival (OS) of 2.5 months (OS of 13.1 months versus 10.6 months, respectively; Hazard Ratio (HR) 0.81; p=0.041) when comp