EISAI RECEIVES EUROPEAN COMMISSION APPROVAL OF INDICATION EXPANSION FOR ANTICANCER AGENT HALAVEN® FOR ADVANCED BREAST CANCER AFTER ONLY ONE PRIOR CHEMOTHERAPY

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that it has received approval from the European Commission of the indication expansion of Halaven® (generic name: eribulin mesylate, “eribulin”) to contribute to 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.

Halaven is currently indicated in Europe for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments. The approval received from the European Commission is for the expansion of the current indication, which was limited to patients who had previously received at least two chemotherapeutic regimens, to include patients with metastatic breast cancer who have had less prior treatment. Through this indication expansion, Halaven will now be able to contribute at an earlier stage to patients with metastatic breast cancer in countries of the European Union.

The approval is based on evidence from two pivotal Phase III studies, including the Phase III clinical study (Study 305: EMBRACE) of Halaven versus treatment of physician’s choice (TPC) in patients with locally advanced or metastatic breast cancer who had previously received at least two to five prior chemotherapeutic regimens including treatments with an anthracycline and a taxane, and a Phase III clinical study (Study 301) of Halaven versus capecitabine in women with locally advanced or metastatic breast cancer who had received prior treatment with an anthracycline and a taxane. These studies involved more than 1,800 patients, making this one of the largest data sets in metastatic breast cancer.

Over 300,000 women are diagnosed with breast cancer

[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