CHINA FOOD AND DRUG ADMINISTRATION ACCEPTS NDA FOR ANTICANCER AGENT HALAVEN®

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the China Food

[Notes to editors]

1. About Halaven (eribulin mesylate)

Halaven is a halichondrin class microtubule dynamics inhibitor with a novel mechanism of action. Structurally Halaven is a simplified and synthetically produced version of halichondrin B, a natural product isolated from the marine sponge *Halichondria okadai*. Halaven is believed to work by inhibiting the growth phase of microtubule dynamics which prevents cell division. In addition, recent non-clinical studies showed that Halaven is associated with increased vascular perfusion and permeability in tumor cores.[3] Halaven promotes the epithelial state and decreases the capacity of breast cancer cells to migrate.[4]

Halaven was first approved as a treatment in the United States in November 2010 for patients with metastatic breast cancer. Halaven is currently approved for use in the treatment of breast cancer in over 60 countries worldwide, including Japan and countries in Europe, the Americas and Asia. Furthermore, Halaven was first approved as a treatment for soft tissue sarcoma in the United States in January 2016, and is approved in countries including Japan and in Europe. Applications seeking approval for use in the treatment of soft tissue sarcoma are currently under review throughout the world including Switzerland, Australia, Brazil, and countries in Asia. Furthermore, Halaven has been designated as an orphan drug for soft tissue sarcoma in the United States and Japan.

Specifically, Halaven is approved for the following indications.

In the United States for the treatment of patients with:

- Metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.
- Unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

In Japan for the treatment of patients with: