

**EISAI SUBMITS APPLICATIONS FOR ANTICANCER AGENT HALAVEN<sup>®</sup>  
SIMULTANEOUSLY IN JAPAN, U.S. AND EUROPE SEEKING  
NEW INDICATION AS TREATMENT FOR SOFT TISSUE SARCOMA**

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

**[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. Halaven has also been approved in countries in Europe and Asia indicated as a treatment for 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 (fat, muscle, nerves, fibrous tissues and blood vessels) in the body. As the structures where the tumors originate are diverse, there are various types of soft tissue sarcoma, and the most common types include leiomyosarcoma, adipocytic and malignant fibrous histiocytoma.

While treatment of soft tissue sarcoma is focused on curati