

No.10-43

August 30, 2010

Eisai Co., Ltd.

EISAI ANNOUNCES EXTENSION OF FDA REVIEW OF DRUG APPLICATION FOR INVESTIGATIONAL AGENT ERIBULIN MESYLATE

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has received notification from the U.S. Food and Drug Administration (FDA) that the agency expects to complete priority review of the eribulin mesylate New Drug Application (NDA) for locally advanced or metastatic breast cancer on or before December 30, 2010, which is a three month extension from the original Prescription Drug User Fee Act (PDUFA) action date of September 30, 2010.

The extension is a result of the agency classifying recent responses to questions regarding the chemistry, manufacturing and controls (CMC) section of the NDA as a major amendment to the NDA. The new action date will give the agency additional time to review the information submitted for this complex synthetic process.

In addition to the U.S. FDA priority review, eribulin is currently under active regulatory review in Japan, the European Union (EU), Switzerland and Singapore.

Eisai defines oncology as a therapeutic area of focus and is committed to developing novel anti-cancer agents and treatments for supportive care. With these efforts, Eisai seeks to further address the diversified needs of patients and families affected by cancer, and their healthcare professionals.

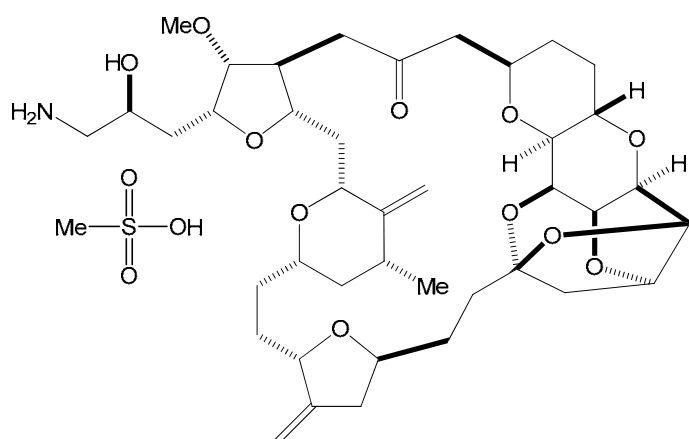
[Please refer to the following notes for further information on eribulin and advanced or metastatic breast Cancer]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

Notes to editors

1. About Eribulin

Eribulin mesylate (E7389) is an investigational agent being evaluated as a potential treatment for locally advanced or metastatic breast cancer. A non-taxane, microtubule dynamics inhibitor, eribulin is a synthetic analog of halichondrin B, which is derived from a natural product isolated from the marine sponge *Halichondria okadae*. Eribulin is the state of the art in modern synthetic chemistry, which has 826 of molecular weight, 62 steps of total synthetic route and 19 chiral carbons.



Eribulin mesylate

2. About Advanced or Metastatic Breast Cancer

Advanced or metastatic breast cancer occurs when a malignant tumor in the breast spreads from its original site to other parts of the body. Approximately 50 percent of women worldwide initially diagnosed with breast cancer are expected to develop recurrent or metastatic disease within 15 years of their first diagnosis. Only one in five women with metastatic breast cancer survives longer than five years. In the U.S., an estimated 155,000 women are currently living with metastatic breast cancer, and that number is projected to increase to 162,000 by 2011.