No. 11-20

March 3, 2011
Eisai Co., Ltd.

THE LANCET PUBLISHES RESULTS FROM PIVOTAL STUDY OF EISAI'S HALAVEN® IN PATIENTS WITH LATE-STAGE METASTATIC BREAST CANCER

Phase III Study Demonstrated that HALAVEN® Met its Primary Endpoint of Overall Survival

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that results from a pivotal study with HALAVEN® (eribulin mesylate), a novel anticancer agent discovered and developed by the company, will be published in the medical journal *The Lancet* [1]. The study being published is the global phase III clinical study "EMBRACE" (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice vs. Eribulin), which showed that HALAVEN® demonstrated a statistically significant increase in overall survival (OS) in women with late-stage metastatic breast cancer. The global study demonstrated that those women treated with HALAVEN® survived a median of 13.1 months compared to 10.6 months for patients who were treated with a single-agent therapy chosen by their physician, which represents a 23% increase in median overall survival. These results from the EMBRACE study support the survival benefits that HALAVEN® may offer to metastatic breast cancer patients in the late stage of their disease.

HALAVEN® is a non-taxane, microtubule dynamics inhibitor that is a synthetic analog of halichondrin B, a natural product that was isolated from the marine sponge *Halichondria okadai* [2), 3)]. Having already obtained regulatory approval from the U.S. Food and Drug Administration and the Singapore Health Sciences Authority, HALAVEN® recently received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use and was granted priority review status in Japan. Regulatory applications seeking approval are also under review in Switzerland and Canada.

The most common side effects (incidence≥25%) reported by patients receiving HALAVEN® were neutropenia (82%), anemia (58%), weakness/tiredness (54%), hair loss (45%), peripheral neuropathy (numbness, tingling or burning in the hand and feet; 35%), nausea (35%), and constipation (25%). The most common serious side effects reported in patients receiving HALAVEN® were neutropenia with or without fever (4% and 2%, respectively). The most common side effect resulting in discontinuation of treatment with HALAVEN® was peripheral neuropathy (5%).

Established more than 180 years ago in 1823, *The Lancet* is a peer-reviewed medical journal published by the British Medical Association. It is considered to be one of the top five general medical journals in the world. *The Lancet* is named after a surgical instrument called a lancet, as well as after the lancet window.

Eisai defines oncology as a therapeutic area of focus and is committed to the development of novel anticancer agents such as HALAVEN® and treatments for supportive care. Through these efforts, Eisai will make further contributions to addressing the diversified needs of and increasing the benefits provided to patients and their families as well as healthcare professionals.

1) Javier Cortes et al, Eribulin monotherapy vs treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomised study, Lancet, 377, 2011. in press
2) Heidi Ledford, Complex Synthesis Yields Breast Cancer Therapy, Nature, 468, 608, 2010.
3) Peter Landers, New Breast Cancer Drug Found Deep in the Sea, Wall Street Journal, January 4, 2011.

[Please refer to the following notes on the Global Phase III Clinical Study, HALAVEN® and the Top Five Medical Journals]

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

[Notes to editors]

1. About the Global Phase III Clinical Study (EMBRACE)

EMBRACE was an open-label, randomized, global, multi-center, parallel-two arm study designed to compare overall survival in patients treated with HALAVEN® (1.4 mg/m^2 administered intravenously for two-to-five minutes on days 1 and 8 of a 21-day treatment cycle) versus a treatment chosen by their physician (control group). The study, which was designed to reflect a "real world" clinical practice, included 762 patients with metastatic breast cancer who previously had been treated with an average of four prior chemotherapies. Ninety-seven percent of patients in the control group received chemotherapy, including vinorelbine (26%), gemcitabine (18%), capecitabine (18%), taxane (16%), anthracycline (9%), and other chemotherapy (10%), while 3% of patients received hormonal therapy. The median age of study participants was 55 (range 27-85).

2. About HALAVEN®

HALAVEN® is a non-taxane, microtubule dynamics inhibitor that is a synthetic analog of halichondrin B, a natural product that was isolated from the marine sponge *Halichondria okadai.* HALAVEN® targets microtubules, the major cytoskeletal component of cells which play a pivotal role in cell replication. It is believed to inhibit the growth phase of microtubule dynamics, which can cause a cell to stop dividing and self-destruct.

3. World's Top Five Medical Journals

- *The New England Journal of Medicine*
- *The Lancet*
- *The Journal of the American Medical Association*
- *Annals of Internal Medicine*
- *British Medical Journal*

(Order based on 2009 Medical Journal Impact Factors)