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Media Inquiries

Judee Shuler

Eisai Inc.

During ASCO: 908-337-2540

201-746-2241 (office)

Cressida Robson

Eisai Europe Ltd.

During ASCO: +44 7908 314 155

Investor Inquiries

Dave Melin

Eisai Inc.

908-255-6378 (cell)

**PHASE III STUDY RESULTS SHOWED EISAI'S ERIBULIN MESYLATE
SIGNIFICANTLY IMPROVED OVERALL SURVIVAL IN PATIENTS WITH LOCALLY
RECURRENT OR METASTATIC BREAST CANCER**

Global EMBRACE Study Compared Eribulin to Treatment of Physician's Choice

Chicago, IL, June 6, 2010 – Results of a Phase III study presented today at the American Society of Clinical Oncology (ASCO) Annual Meeting showed that Eisai's eribulin mesylate significantly improved median overall survival (OS) compared with Treatment of Physician's Choice (TPC) in heavily pre-treated metastatic breast cancer patients.

These results were presented as part of an ASCO-sponsored press briefing; additional details from the study will be presented in an oral session on June 8, 2010 at 9:30 a.m. in East Hall D1 at Chicago's McCormick Place. The study abstract has also been selected for presentation at the 2010 Best of ASCO® Meetings, which will be held in San Francisco and Boston in the United States and in several countries around the world in the months following the ASCO Annual Meeting.

The Phase III "EMBRACE" study (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus Eribulin E7389) met its primary endpoint of overall survival, showing that patients who received eribulin survived a median of 2.5 months longer than patients who received TPC (overall survival of 13.12 months versus 10.65 months, respectively, $p=0.04$). Results from EMBRACE also showed that a secondary endpoint of overall response rate (ORR) was statistically significant. Another secondary endpoint, progression free survival (PFS), was supportive of the primary endpoint but did not reach

statistical significance.

“To date, no single-agent Phase III clinical trial has demonstrated improved survival in women with heavily pre-treated metastatic breast cancer,” said Chris Twelves, M.D., lead investigator for the EMBRACE study and Professor of Clinical Cancer Pharmacology and Oncology from the University of Leeds and St. James’s University Hospital, Leeds, United Kingdom. “These results showed that eribulin significantly improved overall survival versus a variety of agents used in a real-world setting, which previously no single agent has shown.”

The most frequently reported adverse events (AEs) among patients treated with eribulin were asthenia, or fatigue (53.7%), neutropenia, or low white blood cell counts (51.7%), alopecia, or hair loss (44.5%) and peripheral neuropathy, or numbness and tingling in different parts of the body (34.6%).

Treatment-emergent serious AEs were reported for 25 percent of patients in the eribulin group and 25.9 percent of patients in the TPC arm.

About the Study

EMBRACE was an open-label, randomized, multi-center study of 762 patients with locally recurrent or metastatic breast cancer who were previously treated with at least two and a maximum of five prior chemotherapies (≥ 2 for advanced disease), including an anthracycline and a taxane. Patients must have been refractory to the most recent chemotherapy, documented by progression on or within six months of therapy. The study was designed to compare overall survival in patients treated with eribulin versus a TPC arm, reflecting a real-world clinical setting where a variety of agents are used to treat patients with advanced breast cancer.

Patients were randomized in a two-to-one ratio to receive either eribulin (1.4 mg/m^2 administered intravenously for two-to-five minutes on days 1 and 8 of a 21-day treatment cycle) or TPC. TPC was defined as any single agent chemotherapy, hormonal treatment or biological therapy approved for the treatment of cancer; or palliative radiotherapy administered according to local practice. The median age of study participants was 55 (range 27-85); 16 percent of patients had HER2 positive breast cancer and 19 percent had breast cancer that was negative for estrogen, progesterone and HER2 receptors (triple-negative breast cancer).

About Metastatic Breast Cancer

Worldwide, more than one million women a year are diagnosed with breast cancer. 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 United States, an estimated 155,000 women are currently living with metastatic breast cancer, and that number is projected to increase to 162,000 by 2011.

“Women with advanced breast cancer are in critical need of new treatment options,” said Alton Kremer, M.D., Ph.D, Global Head of Clinical Development for Oncology at Eisai Inc. “In this study, eribulin has shown an improvement in survival, and if approved by health authorities, it may offer patients a new treatment option at this stage of the disease.”

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 okadai*.

On March 30, 2010, Eisai announced it had submitted simultaneous regulatory applications for approval of eribulin mesylate for the treatment of locally advanced or metastatic breast cancer to agencies in Japan, the United States and the European Union (EU). The eribulin New Drug Application (NDA) was granted priority review status by the U.S. Food and Drug Administration (FDA) on May 28, 2010.

Eisai Oncology

Eisai Oncology is dedicated to discovering, developing and producing innovative oncology therapies that can make a difference and impact the lives of patients and their families. This passion for people is part of Eisai’s *human health care (hhc)* mission, which strives for better understanding of the needs of patients and their families to increase the benefits health care provides. Our commitment to meaningful progress in oncology research, built on scientific expertise, is supported by a global capability to conduct discovery and preclinical research, and develop small molecules, therapeutic vaccines, biologic and supportive care agents for cancer across multiple indications.

Eisai Inc.

Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business with fiscal year 2009 (year ended March 31, 2010) sales of approximately \$3.9 billion. Eisai’s areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Maryland, Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company’s areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit www.eisai.com.

Eisai Europe, Ltd.

Eisai concentrates its R&D activities in three key areas:

- Integrative Neuroscience, including: Alzheimer's disease, multiple sclerosis, neuropathic pain, epilepsy, depression
- Integrative Oncology, including: anticancer therapies; tumor regression, tumor suppression, antibodies and supportive cancer therapies; pain relief, nausea
- Vascular/Immunological reaction, including: acute coronary syndrome, atherothrombotic disease, severe sepsis, rheumatoid arthritis, psoriasis, Crohn's disease

In Europe, Eisai undertakes sales and marketing operations in over 20 markets, including the United Kingdom, France, Germany, Italy, Spain, Switzerland, Sweden, Ireland, Austria, Denmark, Finland, Norway, Portugal, Iceland, Czech Republic, Hungary and Slovakia.

Eisai Co., Ltd.

Eisai Co., Ltd. is a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world. Through a global network of research facilities, manufacturing sites and marketing subsidiaries, Eisai actively participates in all aspects of the worldwide health care system. Eisai employs approximately 11,000 employees worldwide.

For further information, please visit www.eisai.co.jp.

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