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Eisai Co., Ltd.


Eisai Medical Research Inc. (Headquarters: New Jersey, President and CEO: Mindell Seidlin), which is a clinical research subsidiary of Eisai Co., Ltd. of Tokyo (President and CEO: Haruo Naito) presented the latest analysis result of safety and efficacy for E7389 in the treatment of advanced, refractory breast cancer during the San Antonio Breast Cancer Symposium. E7389 is a synthetic analog of halichondrin B(HB), which is a natural marine product extracted from marine sponge Halichondria okadai, and had shown in preclinical studies to have highly potent anti-cancer activity in vitro and in vivo.

The purpose of this clinical trial was to evaluate E7389 as a monotherapy in patients with refractory breast cancer. The primary endpoint of this trial was response rate, measured using the RECIST (Response Evaluation Criteria In Solid Tumors) criteria-a group of standards used to measure responses to treatment in solid tumors.

Seventy-one women were enrolled in a clinical trial for 28 days as 1 cycle (unit for dosing period). The latest efficacy data for 65 patients, and safety data on 48 patients are available.

Sixty-five patients considered evaluable for response had completed at least 2 cycles and had a tumor assessment, which could be compared to their baseline.

Of the 65 evaluable patients, 10 partial responses (PR, 50% reduction in tumor size) were confirmed in the 4th cycle, and 21 stable disease cases (SD) were confirmed. It is expected for the potential response rate of 15% in advanced, refractory breast cancer patients to be a novel anticancer drug.

From the result of this test, the predominant adverse event related to E7389 was neutropenia. Other adverse events were mild to moderate nausea, fatigue, dehydration, arthralgias, dyspnea and neuropathy. Meanwhile, none of the patients were discontinued due to hematological toxicity.

This trial is still ongoing, and will achieve the final results when the study is completed. Currently, the E7389 late Phase II trial which aims to apply for an filing under Subpart H is ongoing.
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[Press Release by Eisai Inc. is attached for reference]
Eisai Announces Phase II Data on E7389, a Potential New Therapy for the Treatment of Breast Cancer

Marine Sponge Molecule is Model for Novel Anti-Tubulin Agent

SAN ANTONIO, DECEMBER 8, 2005—Researchers today presented preliminary safety and efficacy data for E7389 in the treatment of advanced, refractory breast cancer during the San Antonio Breast Cancer Symposium. E7389 is a synthetic analog of halichondrin B (HB), which is a natural product shown in preclinical studies to have highly potent anti-cancer activity in vitro and in vivo. Halichondrin B was originally isolated from a type of marine sponge.

This study was designed to evaluate E7389 as a monotherapy in patients with refractory breast cancer. The primary endpoint of this trial was response rate, measured using the RECIST (Response Evaluation Criteria In Solid Tumors) criteria – a group of standards used to measure responses to treatment in solid tumors.

Of the 65 evaluable patients, 10 partial responses were confirmed at the 4th cycle assessment. Twenty-one patients had stable disease (SD). In treatment-refractory patients with advanced breast cancer this preliminary response rate (15%) appears promising.

Based on the preliminary results of this study, the predominant serious side effect related to E7389 was neutropenia (low white blood cell counts). Other side effects were considered mild to moderate and included nausea, fatigue, dehydration, arthralgias, dyspnea and neuropathy. None of the patients discontinued the study due to hematological toxicity.

“The results from this study with E7389 appear promising, and clinical research on E7389 as a treatment for breast cancer is continuing,” said Sandra Silberman, MD, PhD, Associate Vice President and Global Therapeutic Area Head, Oncology at Eisai Medical Research, Inc. “E7389 is an example of Eisai’s human health care (hhc) commitment to satisfy unmet medical needs of patients and their families. Eisai has targeted oncology/critical care as one of three key therapeutic areas of focus,” she added.

Seventy-one women were enrolled in the 28-day cycle patient group. Preliminary efficacy data for 65 patients and safety data on 48 patients are available. The 65 patients considered evaluable for response had completed at least their 2nd cycle of treatment and had a tumor assessment, which could be compared to their baseline. This study is ongoing, and final results may change from the initial analysis.

“My colleagues and I are very excited by the results of this study so far,” said Linda T. Vahdat, MD, Associate Professor of Clinical Medicine and Medical Director,
Breast Cancer Program at Cornell University New York Presbyterian Hospital. “We look forward to additional studies with this novel compound.”

Pre-clinical studies demonstrate that E7389 suppresses the growth of cellular microtubules, which are essential for cell division. By doing so, E7389 appears to stop the production of new cancer cells and ultimately results in the programmed death of the existing cancer cells, a process known as apoptosis.

**Breast Cancer**

In spite of recent developments in the treatment of advanced breast cancer, it remains incurable. It is a major health care problem due to its high incidence: approximately 212,000 new cases of invasive breast cancer will be diagnosed in 2005 in the US, and in 2005 an estimated 40,870 people will die from breast cancer. Although mammographic screening advances the time of diagnose, 20-89% of those diagnosed at an early phase, depending on stage and treatment, develop metastases within five years. Developing new and well-tolerated drugs for the control of advanced, relapsed or refractory breast cancer is a justified endeavor and a continuous challenge to the pharmaceutical industry.

**E7389: A Cooperative Research and Development Program**

E7389 was developed through a cooperative program between the National Cancer Institute (NCI) and Eisai Research Institute (ERI) in Andover, Massachusetts. In 1992, ERI scientists determined that the anticancer activity of HB resides in one half of the molecule. E7389 was finally isolated following the synthesis of more than 200 analogues of this anticancer half. ERI and the NCI entered into a cooperative research and development agreement (CRADA) in 2001 and the first Phase I study of E7389 was initiated in 2002. Eisai initiated two Phase I studies of E7389 in 2003, and Phase II studies began in 2004.

**About Eisai Medical Research Inc.**

Eisai Medical Research Inc. is a U.S. pharmaceutical subsidiary of Eisai Co., Ltd. Eisai Co., Ltd. is a research – based human health care company that discovers, develops and markets products in more than 30 countries. Eisai Medical Research Inc. was established to focus solely on clinical research and to expedite clinical drug development of new chemical entities and of new indications for marketed products.