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Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

GLOBAL PHASE III STUDY RESULTS SHOW ERIBULIN MEETS PRIMARY ENDPOINT OF OVERALL SURVIVAL

Eisai Plans to Submit Marketing Authorization Applications for Eribulin Mesylate in Locally Advanced or Metastatic Breast Cancer

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) today announced preliminary results from a recently completed Phase III study with E7389 (generic name: eribulin mesylate, "eribulin"), discovered and developed by the Company, in patients with locally advanced or metastatic breast cancer.

This global Phase III study, known as "EMBRACE," (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389), was an openlabel, randomized, parallel two-arm, multi-center study of 762 women with locally recurrent or metastatic breast cancer previously treated with at least two and a maximum of five prior chemotherapy regimens, including an anthracycline and a taxane.

The patients were treated either with eribulin (administered intravenously over two to five minutes on days 1 and 8 every 21 days) or with treatment of physician's choice. Treatment of physician's choice is defined as any single agent chemotherapy, hormonal treatment or biological therapy approved for the treatment of cancer; or palliative treatment or radiotherapy administered according to local practice.

Preliminary results from the study demonstrated a statistically significant improvement in overall survival, the primary endpoint, in eribulin-treated patients compared with the physician's choice of therapy. The safety profile of eribulin of this Phase III study was consistent with the adverse events seen in previous Phase II clinical studies and the most common adverse event reported was myelosupression.

Eribulin is a new chemical compound discovered and developed by Eisai. It is a synthetic analogue of halichondrin B, a naturally-derived compound that was first isolated from a marine sponge. While taxanes inhibit cell division by stabilising microtubules, eribulin is a microtubule dynamics inhibitor that arrests the cell cycle through inhibition of the growth of microtubules without interfering with microtubule shortening.

While early detection by breast cancer screening and the development of innovative anti-cancer drugs have contributed to the decline in breast cancer mortality around the world, breast cancer remains one of the leading causes of cancer death in women. Although advances are being made every year in the treatment of breast cancer, women with locally advanced or metastatic breast cancer have limited treatment options and the development of more effective treatment or anti-cancer drugs is critically important.

Eisai will complete a more detailed analysis of the data prior to submitting marketing authorization applications for eribulin to health authorities in Japan, the United States, and Europe for locally advanced and metastatic breast cancer by the end of the fiscal year 2009.

Eisai is currently conducting clinical trials of this compound in-house to evaluate the efficacy and safety not only in breast cancer, but also in non-small cell lung cancer (NSCLC), hormone refractory prostate cancer, and sarcoma. Eisai also includes eribulin as one of the compounds in the co-development projects based on the strategic collaboration agreement with Quintiles and will proceed with joint clinical development of this compound for NSCLC as well as bladder cancer.

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 will make further contributions to addressing the diversified needs of and improving benefits to patients and families affected by cancer as well as healthcare professionals.

[Please refer to the following notes for a glossary of terms]

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<Notes to editors>

About locally advanced and metastatic breast cancer

Breast cancer is staged from Stage 0 to Stage IV, based on the size of the breast lump, whether lymph nodes are involved, and whether the distant metastases have developed. Locally advanced breast cancer, also known as Stage III, is invasive breast cancer that has spread to axillary lymph nodes, the chest wall, skin of the breast, or above or below the collarbone. Metastatic breast cancer, considered Stage IV, is diagnosed when cells from the original breast tumour have spread beyond the breast to other parts of the body, usually the liver, bone, brain, liver, or lungs.

It is believed that more than one million women are newly diagnosed with breast cancer each year around the world. The number of those women in G7 countries is estimated to be a little less than 460,000, of which up to 40% is thought to develop locally advanced or mestastatic breast cancer.

About overall survival

Overall survival is defined as the time from the date of randomisation until the date of death from any cause.