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Eisai Co., Ltd.

EISAI PRESENTS NEW QUALITY OF LIFE FINDINGS IN PATIENTS WITH METASTATIC BREAST CANCER FROM HALAVEN® (ERIBULIN) VERSUS CAPECITABINE STUDY AT 49TH ASCO ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today at the 49th Annual Meeting of the American Society of Clinical Oncology (ASCO) new findings showing that Halaven® (eribulin mesylate, "eribulin") improved overall quality of life (QOL) (Global Health Status and QOL, "GHS/QOL") significantly more than capecitabine over the course of a Phase III study (Study 301) in patients with metastatic breast cancer who had been previously treated with anthracyclines and taxanes.

The findings presented were based on an analysis of responses to questions on QOL related to the symptoms, functioning, and overall well-being of those patients who participated as subjects in Study 301. The GHS/QOL score results, which indicate overall patient QOL, were shown to improve significantly more for patients administered eribulin versus capecitabine ($p=0.048$) over the course of treatment. Eribulin also performed significantly better than capecitabine in assessments of cognitive functioning ($p<0.001$), nausea and vomiting ($p=0.043$), and diarrhea ($p=0.001$). In comparison, capecitabine performed significantly better compared to eribulin in evaluations of emotional functioning ($p=0.033$), systemic side effects ($p<0.001$), and upset by hair loss ($p=0.023$).

Cancer and its treatment have a major impact on patient QOL such as difficulties with family life and fulfilling family roles, demonstrating ability at work, and participation in common social activities. A central goal in developing novel therapies for patients with metastatic breast cancer is to extend life for as long as possible while ensuring that optimal patient QOL is maintained. Effective QOL management is also important because it allows the treatment to continue, thus enabling the maximum benefits of the treatment to be provided to patients.

All QOL data collected in the study serve to offer a better understanding on how the QOL of patients with breast cancer may be affected by either treatment, and Eisai believes that the findings will serve as a valuable reference for making informed decisions when considering which treatment to undergo. The company remains committed to providing further clinical evidence for eribulin aimed at maximizing value of the drug as it seeks to contribute further to addressing the diverse needs of, and increasing the benefits provided to, patients with cancer, their families, and healthcare providers.

[Please refer to the following notes for further information on the Study 301 QOL assessments, the assessment scales used, and Halaven.]

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[Notes to editors]

1. About the Study 301 QOL Assessments

Study 301 was an open-label, randomized, two-parallel-arm, multicenter study designed to evaluate Halaven versus capecitabine in 1,102 women with locally advanced or metastatic breast cancer who had up to three prior chemotherapy regimens in the (neo)adjuvant setting, and no more than two prior regimens for locally advanced and/or metastatic disease. The regimens must have included an anthracycline and a taxane. Although eribulin did not achieve a statistically significant result when compared to capecitabine in terms of overall survival (OS) and progression-free survival (PFS), the co-primary endpoints of the study, eribulin did demonstrate a trend favoring improved OS (eribulin median OS: 15.9 months, capecitabine median OS: 14.5 months; HR 0.879; 95% CI: 0.770-1.003; p=0.056). Additionally, a later PFS assessment carried out by an independent evaluation body concluded that there was no significant difference between the two drugs (eribulin median PFS: 4.1 months, capecitabine median PFS: 4.2 months, HR 1.079; 95% CI: 0.932-1.250; p=0.305).

Study 301 had a secondary endpoint of quality of life (QOL) assessed using the EORTC QLQ-C30 and QLQ-BR23 questionnaires at baseline, 6 weeks, and 3, 6, 12, 18 and 24 months after starting treatment (or until progressive disease or treatment change) and at unscheduled visits. Longitudinal analyses were carried out, with the primary endpoint being change from baseline for overall QOL (GHS/QOL) and exploratory endpoints being change from baseline for a range of functions and signs/symptoms.

2. About the QOL Assessment Scales Used

The EORTC QLQ-C30 and EORTC QLQ-BR23 quality of life questionnaires (QLQ) used in the study are widely used in international clinical trials and research as scales for assessing the QOL of patients with breast cancer. They include not only a scale for assessing functioning, which is common when assessing the QOL of patients with cancer, but also include a subjective scale related to patient symptoms, which is an additional, clinically useful advantage.

EORTC QLQ-30 includes five functional scales (physical, role, emotional, social, and cognitive), three symptom scales (fatigue, nausea and vomiting, and pain) and one global health status scale, numbering 30 questions in total. High scores on the functional scales indicate a high level of functioning and high scores on the global health status indicate a high QOL. In contrast, high scores on the symptom scales/items indicate high levels of health problems.

EORTC QLQ-BR23 is a specific questionnaire containing 23 items measuring functioning and symptoms related to breast cancer, such as symptoms of side effects, body image, and other areas related to overall physical and other items. It is administered in addition to the core questionnaire (EORTC QLQ-C30).

3. About Halaven® (eribulin mesylate)

Halaven, a non-taxane, microtubule dynamics inhibitor with a novel mechanism of action, belongs to a class of antineoplastic agents, the halichondrins, which are natural products isolated from the marine sponge *Halichondria okadai*. It is believed to work by inhibiting the growth phase of microtubule dynamics without affecting the shortening phase and sequestering tubulin into nonproductive aggregates.

In a Phase III clinical study (EMBRACE) conducted overseas of Halaven versus treatment of physician's choice (TPC) in 762 patients with advanced or recurrent breast cancer previously treated with an anthracycline and a taxane, Halaven indicated an extended overall survival (OS) of 2.5 months (OS of 13.1 months versus 10.6 months, respectively; Hazard Ratio (HR) 0.81; p=0.041) when compared to TPC. An updated analysis of OS (not protocol-specified) in the EMBRACE study was also performed at the request of European and U.S. regulatory authorities. These results demonstrated an increase of 2.7 months in OS for Halaven compared with TPC (OS of 13.2 months versus 10.5 months, respectively; HR 0:81; p=0.014). The most common adverse reactions (events with an

incidence rate of at least 25%) among patients treated with Halaven were asthenia (fatigue), neutropenia, anemia, alopecia (hair loss), peripheral neuropathy (numbness and tingling in arms, legs and/or other parts of the body), nausea and constipation. The most common serious side effects reported in patients receiving Halaven were neutropenia with or without fever (4% and 2%, respectively). The most common adverse reaction resulting in discontinuation of treatment with Halaven was peripheral neuropathy (5%). Furthermore, in a Phase II clinical study conducted in Japan, Halaven was found to possess excellent anticancer effects and tolerability in patients with advanced or recurrent breast cancer who had previously undergone treatment.

Halaven was first approved as a treatment for breast cancer in the United States in November 2010, and is approved in more than 40 countries worldwide, including European Union member states, Japan, Singapore and Switzerland. In Japan, the drug has been approved to treat inoperable or recurrent breast cancer and was launched in the country in July 2011. Furthermore, with the aim of maximizing value of the drug, Eisai is currently moving ahead with developments investigating the potential of Halaven as a therapy in the treatment of breast cancer with fewer prior treatments as well as soft-tissue sarcoma and non-small cell lung cancer.