No.14-31

June 2, 2014
Eisai Co., Ltd.

EISAI PRESENTS DATA ON HALAVEN® FROM POOLED ANALYSIS OF OVER 1,800 ADVANCED BREAST CANCER PATIENTS AT 50TH ASCO ANNUAL MEETING

SIGNIFICANT IMPROVEMENT IN OVERALL SURVIVAL FOUND IN HER2 NEGATIVE AND TRIPLE NEGATIVE BREAST CANCER PATIENTS

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has presented data from a pooled analysis of two randomized open-label Phase III clinical studies (the EMBRACE study and Study 301) on the use of Halaven® (generic name: eribulin mesylate, "eribulin"), a non-taxane microtubule dynamics inhibitor, in patients with locally advanced or metastatic breast cancer who had progressed after receiving prior therapy including an anthracycline and a taxane in either the adjuvant or metastatic setting, at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO).

One of the largest data sets in metastatic breast cancer, the pooled analysis examined data from two pivotal Phase III clinical studies of more than 1800 women. Analysis was conducted on Overall Survival (OS) divided into subgroups consisting of HER2 (Human Epidermal Growth Factor Receptor Type 2) negative patients, HER2 positive patients and triple negative (does not express the genes for estrogen receptor, progesterone receptor and HER2) patients.

Overall, eribulin demonstrated a significant improvement in OS vs control (Hazard Ratio (HR) 0.85; 95% CI: 0.77-0.95; p=0.003; median OS: 15.2 vs 12.8 months). For the specific subgroups, a significant OS benefit was found in women with HER2 negative breast cancer (HR 0.82; 95% CI: 0.72-0.93; p=0.002; median OS: 15.2 vs 12.3 months) and in women with triple negative breast cancer (HR 0.74; 95% CI: 0.60-0.92; p=0.006; median OS: 12.9 vs 8.2 months). However no significant difference was found in women with HER2 positive breast cancer (HR 0.82; 95% CI: 0.62-1.06; p=0.135; median OS: 13.5 vs 12.2 months). There were no noticeable differences in the tolerability and safety data previously shown in the EMBRACE and 301 studies.

Eribulin remains the only chemotherapy proven to improve significantly overall survival in women with advanced breast cancer after either adjuvant or metastatic anthracycline and taxane treatment. Despite the HER2 negative subtype affecting an estimated 85% of women with breast cancer, there are often few effective treatment options for HER2 negative and triple negative advanced breast cancer. These new data suggest that eribulin could benefit these underserved advanced breast cancer patients.

On May 26th, 2014, Eisai's U.K. subsidiary Eisai Europe Limited received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) on its application requesting an indication expansion of eribulin for use in earlier-line treatment of advanced breast cancer.

The positive opinion received from the CHMP is a recommendation to expand the indication to include patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.

Eisai 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 Halaven, the pooled analysis, Study 305, Study 301 and HER2.]

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[Notes to editors]

1. 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. Halaven was first approved as a treatment for breast cancer in the United States in November 2010, and is approved in more than 50 countries worldwide, including European Union member states, Japan, Singapore and Switzerland. 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.

2. About the pooled analysis

The pooled analysis included data from EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Treatment of Physician's Choice (TPC) Versus Eribulin) and involved women who received 2-5 lines of chemotherapy for advanced disease. In this third line setting, women were randomized 2:1 to receive eribulin (1.4 mg/m^2 iv on days 1 and 8 every 21 days) or TPC. The second study in the pooled analysis (study 301) included women who had received 0-2 prior chemotherapies for advanced disease who were randomized 1:1 to receive either eribulin (dose schedule as per EMBRACE) or capecitabine (1.25 g/m^2 orally twice daily on days 1-14 every 21 days). Overall survival was analyzed in the overall intent-to-treat (ITT) population and in subgroups based on HER2 and hormone-receptor status.

3. About Study 305 (EMBRACE)

In the Phase III clinical study (Study 305, EMBRACE) of Halaven versus treatment of physician's choice (TPC) in 762 patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane, Halaven indicated 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 selected, major existing therapies. 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, 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. The most common adverse reaction resulting in discontinuation of treatment with Halaven was peripheral neuropathy (5%).

4. About Study 301

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). In regard to safety, adverse events (AEs) were consistent with the known side-effect profiles of both drugs. The most common AEs (events with an incidence rate of at least 20%) for Halaven and capecitabine were, respectively, neutropenia (54.2% vs. 15.9%), hand-foot syndrome (0.2% vs. 45.1%), alopecia (34.6% vs. 4.0%), leukopenia (31.4% vs. 10.4%), diarrhea (14.3% vs. 28.8%), and nausea (22.2% vs. 24.4%).

5. About HER2 (Human Epidermal Growth Factor Receptor Type 2)

HER2 is a protein that is found on the surface of cells. In HER2-positive breast cancer there is more (over expression) of this protein found on the surface of tumor cells compared with normal breast cells. This protein can be targeted with HER2 targeted therapies in people who overexpress HER2, but not in people with normal levels of HER2 protein (HER2-negative) breast cancer. Breast cancers are routinely tested for the presence of HER2 to decide the most appropriate treatment. HER2 negative breast cancer is a subtype that affects an estimated 85% of women with breast cancer. Triple-negative breast cancer (TNBC) refers to any breast cancer that does not express the genes for estrogen receptor, progesterone receptor and HER2.