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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.

E7389 Demonstrated Anti-tumor Activity in Heavily Pretreated Patients with Advanced Breast Cancer

- Phase II Data Presented at ASCO Showed Acceptable Tolerability Profile, with Low Incidence of Grade 3 and 4 Neuropathy -

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that the investigational chemotherapeutic agent E7389 (generic name: eribulin mesylate) demonstrated activity in a heavily pretreated population of women with locally advanced or metastatic breast cancer, according to results of a multi-center Phase II clinical trial. The study also suggests that E7389 has a manageable tolerability profile, with a low incidence of Grade 3 (severe) and no Grade 4 (disabling or life-threatening) neuropathy. These data (abstract #1084) will be presented at the 44th Annual Meeting of the American Society of Clinical Oncology (ASCO) on Monday, June 2 from 2 to 6 p.m. at S Hall A1 of McCormick Place.

"The anti-tumor activity of E7389, as observed in this study, is encouraging, given the limited treatment options for women with advanced breast cancer who have previously received multiple lines of therapy," said lead investigator Linda T. Vahdat, MD, of Weill Cornell Medical College in New York. "The subjects in this trial had received a median of four prior chemotherapy regimens that included an anthracycline, a taxane and capecitabine."

About Study 211
Study 211 is a Phase II, open-label, single-arm study evaluating the efficacy and safety of E7389 in patients with locally advanced or metastatic breast cancer who had received an anthracycline, a taxane and capecitabine as prior therapy, and who were refractory to their last chemotherapy regimen, as documented by progression on or within six months of that therapy.

Of 299 patients enrolled in the study, 291 were treated with E7389. The median age of those patients was 56 years (range: 26-80 years). E7389 was administered at a dose of 1.4mg/m2 as a 2- to 5-minute intravenous infusion on Days 1 and 8 of a 21-day cycle. Patients received a median of four cycles of E7389 (range 1-27). No premedication to prevent hypersensitivity was required.

Two-hundred sixty-nine patients met the key inclusion criteria. In patients who received a median of four cycles of E7389, Overall Response Rate (ORR) by Independent Review (IR) was 9.3% (all Partial Responses (PR); 95% confidence interval [CI]: 6.1%-13.4%). Investigator-assessed ORR was 14.1% (1 CR; 95% CI: 10.2%-18.9%). Nearly half (46.5%)

the patients had stable disease (SD) after treatment with E7389. The clinical benefit rate (CBR, defined as CR+PR+SD ≥6 months) was 17.1% (95% CI: 12.8%-22.1%).

The median duration of response was 4.2 months (126 days, range: 42* -258 days; 95% CI: 86-147). Median progression-free survival (PFS) was 2.6 months (79 days, range: 1*-397 days) , and the median overall survival (OS) rate was 10.3 months (315 days, range: 19-604 days; 95% CI: 279-350). The six-month PFS and OS rates were 16.0% (95% CI: 8.6-17.0) and 72.3%, respectively (95% CI: 66.9-77.6).

The safety analysis included all 291 patients who received treatment with E7389. Patients with up to Grade 2 peripheral neuropathy were included in the study. The most frequently reported Grade 3 (severe) or Grade 4 (disabling or life-threatening) adverse events were neutropenia (a decrease in the number of granular white blood cells, 54%); febrile neutropenia, 5.5%, leukopenia (low white blood cell count, 14%), and weakness/fatigue (10%; no Grade 4 events). Grade 3 peripheral neuropathy (a functional disturbance or damage to nerves outside the brain and spinal cord) was reported in 5.5% of patients. No Grade 4 peripheral neuropathy events were reported. No correlation was seen between Grade 2 peripheral neuropathy and deterioration.

”In this study, E7389 appeared to have an acceptable tolerability profile, particularly with regard to the low incidence of peripheral neuropathy,” noted Vahdat. “None of the reported cases of neuropathy were disabling, suggesting that E7389, if approved, may be a useful addition to the treatment armamentarium for advanced breast cancer.”

[Please see the following note for information about E7389]

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<Note to Editor>

About E7389
E7389 is being developed by Eisai as a potential new chemotherapeutic agent. It suppresses the growth of microtubules, which are involved in various cellular processes in the body, such as cell division. E7389 is a synthetic analog of halichondrin B, a naturally occurring compound which was first isolated from a marine sponge *Halichondria okadai* in 1992.