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Eisai Europe Limited

Eribulin Mesylate Demonstrated Anti-Tumor Activity in Heavily Pretreated Patients With Advanced Breast Cancer

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London (ots/PRNewswire) - - Phase II Data Presented at ASCO Showed Acceptable Tolerability Profile, with Low Incidence of Grade 3 and 4 Neuropathy

Eisai Europe Ltd. The investigational chemotherapeutic agent eribulin mesylate (E7389) 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 eribulin mesylate 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-tumour activity of eribulin mesylate, 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 (Data on file)

Study 211 is a Phase II, open-label, single-arm study evaluating the efficacy and safety of eribulin mesylate 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 eribulin mesylate. The median age of those patients was 56 years (range: 26-80 years). Eribulin mesylate 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 eribulin mesylate (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 eribulin mesylate, 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 eribulin mesylate. The clinical benefit rate (CBR, defined as CR+PR+SD equal to or more than 6 months) was 17.1% (95% CI: 12.8%-22.1%).

The median duration of response was 4.2 months (126 days, range: 42(1)-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 eribulin mesylate. 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, eribulin mesylate 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 eribulin mesylate, if approved, may be a useful addition to the treatment armamentarium for advanced breast cancer."

Note to Editors

About Eribulin Mesylate (Data on file)

Eribulin mesylate 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. Eribulin mesylate is a synthetic analog of halichondrin B, a naturally occurring compound which was first isolated from a marine sponge *Halichondria okadae* in 1992.

About Eisai Europe Ltd.

Established in 1989, Eisai Europe Ltd. is the European pharmaceutical subsidiary of Eisai Co. Ltd., a research-based human health care (hhc) company that discovers, develops and markets products throughout the world. Through a global network of research facilities, manufacturing sites and marketing subsidiaries, Eisai actively participates in all aspects of the worldwide health care system. Eisai focuses its efforts in two main therapeutic areas; integrative neurology and integrative oncology/critical care. Eisai employs more than 9,500 people worldwide.

(1) Censored observation.

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