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Eisai reveals phase III results of breast cancer drug Halaven

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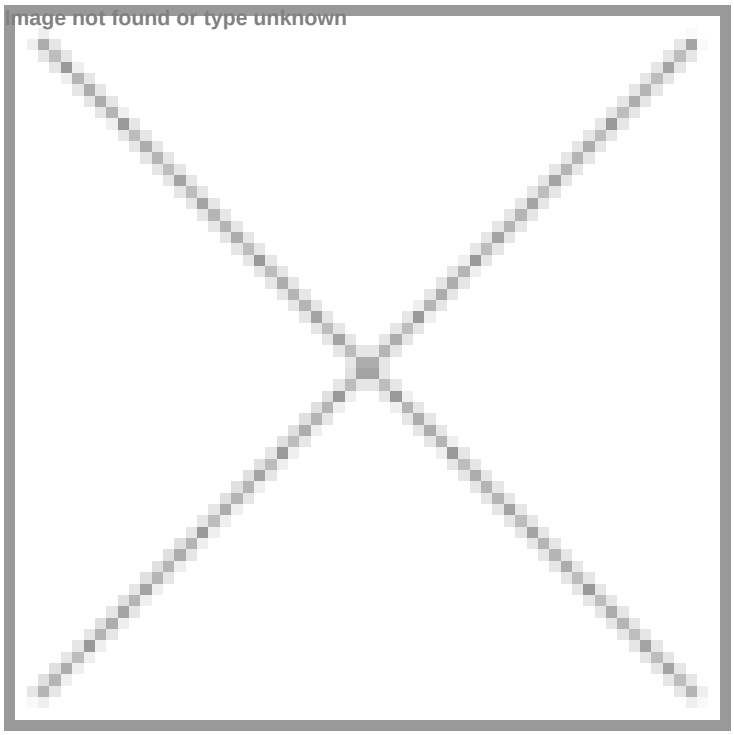

Singapore: Eisai revealed its preliminary results from a recently completed phase III study of Halaven versus capecitabine (Xeloda) in women with locally advanced or metastatic breast cancer.

The trial did not meet the pre-specified criteria for either of the co-primary endpoints of overall survival (OS) and progression-free survival (PFS), however, it showed a trend towards improved OS for patients who received Halaven when compared with capecitabine. The improvement was not statistically significant and no difference was seen in PFS.

Eisai is conducting a detailed analysis of the data, including the secondary endpoints and subgroups pre-specified in the study protocol, and plans to discuss the data with health authorities toward potential regulatory filing. Full study results will be submitted for presentation at an upcoming medical meeting.

Dr Kenichi Nomoto, president, oncology product creation unit, Eisai, said that, "It is important to note that this was a head-to-head comparison designed to show superiority against a commonly used drug approved in an earlier line of therapy than the FDA-approved indication for Halaven. We will look closely at the full data results to determine meaningful learnings for the medical community. Eisai remains committed to evaluating the safety and efficacy of eribulin in patients living with locally advanced or metastatic breast cancer, an area of significant unmet medical need."

The global phase III trial (Study 301) was an open-label, randomized, two-parallel-arm, multicenter study of 1,102 women

with locally advanced or metastatic breast cancer previously treated with anthracyclines and taxanes either in the (neo) adjuvant setting or for locally advanced or metastatic disease.

The study included patients with zero to two previous chemotherapies for advanced disease. Patients were randomized at a ratio of 1:1 to receive treatment with Halaven or capecitabine in accordance with their HER2/neu status and geographic region.

Patients received either Halaven 1.4mg/m2 (administered intravenously over two to five minutes on days one and eight, every 21 days) or capecitabine 2.5g/m2/day (administered orally twice daily in two equal doses on days one-to-14, every 21 days). Adverse events observed in the trial were consistent with the known safety profile of Halaven found in the full prescribing information.