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Eisai Co., Ltd.

EISAI ANNOUNCES TOP-LINE PHASE III TRIAL RESULTS OF ERIBULIN IN PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER FOLLOWING AT LEAST TWO PRIOR REGIMENS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today top-line results of the investigational Phase III study (Study 302) of its in-house developed anticancer agent eribulin mesylate ("eribulin," Brand name: Halaven®) in patients with advanced non-small cell lung cancer (NSCLC) that has progressed following two or more prior treatment regimens.

Study 302 was a global, multicenter, randomized, open-label Phase III trial comparing the efficacy and safety of eribulin with a single treatment of physician's choice (TPC) consisting of either docetaxel, pemetrexed, gemcitabine or vinorelbine in 540 patients with advanced NSCLC and disease progression following at least two prior regimens for advanced disease, which included a platinum-based regimen.

The preliminary analysis of the study showed that Study 302 did not meet its primary endpoint of improving overall survival (OS); the median OS in both arms was 9.5 months (Hazard Ratio 1.16; $p=0.1343$). The preliminary safety analysis showed that the most common adverse reactions in the eribulin arm were decreased appetite, neutropenia, alopecia, nausea and fatigue, which were consistent with the known side-effect profile of eribulin.

"We know that NSCLC is a difficult-to-treat tumor type with no chemotherapy recognized as a standard treatment following two prior regimens. This is a disease which still has significant unmet medical needs," said Kenichi Nomoto, PhD, President, Oncology Product Creation Unit, Eisai Product Creation Systems. "While eribulin did not show an improvement in OS compared to TPC in this study, the trial demonstrates that eribulin has anticancer activity in advanced NSCLC patients following at least two prior regimens and further analyses of the results are ongoing. These results do not affect the current approved indications for Halaven."

Detailed results of the study will be presented at a future academic conference.

Eribulin, first in the halichondrin class of microtubule dynamics inhibitors with a novel mechanism of action, was first approved as a treatment for metastatic breast cancer in the United States in November 2010, and is approved in more than 50 countries worldwide, including countries in Europe and Asia, as well as Japan. Eisai remains committed to the therapeutic area of oncology and to continued research with eribulin in order to help contribute to the lives of patients and their families.

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