

LENVATINIB PHASE III RESULTS SHOW SIGNIFICANT IMPROVEMENT IN PROGRESSION-FREE SURVIVAL IN PATIENTS WITH RADIOIODINE-REFRACTORY DIFFERENTIATED THYROID CANCER

Phase III data for lenvatinib to be presented in a Head and Neck Cancer oral session at ASCO

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today the results from the Phase III SELECT trial of lenvatinib (E7080), a novel investigative anti-cancer agent for patients with progressive radioiodine-refractory differentiated thyroid cancer (RR-DTC). Progression-free survival (PFS) with lenvatinib was extended significantly compared to placebo (Hazard Ratio (HR) 0.21; 99% CI: 0.14-0.31; $p < 0.0001$). The median PFS with lenvatinib and placebo were 18.3 months and 3.6 months respectively. These data will be presented at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) in a Head and Neck Cancer oral session on Monday, June 2, and as part of the official press program on Saturday, May 31 (Abstract No. LBA6008).

Lenvatinib is an oral multiple receptor tyrosine kinase (RTK) inhibitor with a novel binding mode that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors, in addition to other proangiogenic and oncogenic pathway-related RTKs involved in tumor proliferation. The SELECT (Study of E7080 "LEnvatinib" in Differentiated Cancer of the Thyroid) study confirmed a statistically significant benefit for treatment with lenvatinib on PFS in all predefined subgroups. Secondary endpoints included overall response rate (ORR*), overall survival (OS) and safety. Rates of complete response were 1.5% (4 patients) for the lenvatinib group and zero in the placebo group. The results for partial response S ro in exposure duration was 13.8 months for lenvatinib, 3.8 months for placebo, and the median time to response for lenvatinib was 2.0 months. rS a.e TJ-25.5449 -1.2994 TD-.0001 Tc.0636 Tw(hyperten)5.2(s)-3.1(io)5.2(n (4

[Please refer to the following notes on lenvatinib, the SELECT study and thyroid cancer.]

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[Notes to editors]

1. About Lenvatinib (E7080)

Lenvatinib, discovered and developed by Eisai, is an oral multiple receptor tyrosine kinase (RTK) inhibitor with a