

EISAI RECEIVES EUROPEAN COMMISSION APPROVAL OF ANTICANCER AGENT LENVIMA[®] FOR TREATMENT OF ADVANCED THYROID CANCER REFRACTORY TO RADIOACTIVE IODINE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.K. subsidiary Eisai Europe Ltd. has received approval from the European Commission (EC) for anticancer agent Lenvima[®] (lenvatinib mesylate) in the treatment of adult patients with progressive, locally advanced or metastatic differentiated (papillary, follicular, Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). Lenvima was granted an accelerated assessment by the European Medicines Agency, and was ultimately approved in approximately 9 months since the application was filed on August 14, 2014.

The decision by the EC was based on the results of a mu median PFS in the Lenvima group: 18.3 months; median PFS in the placebo group: 3.6 months; Hazard Ratio (HR) 0.21 [99% CI: 0.14-0.31]. In addition, the study underlines the rapid resT0tudy u7 n]TJ0T51e1d in 1.5% (4 patients) of the Lenvima group and none of the placebo group. Common Lenvima treatment-related adverse events were hypertension, decreased appetite, weight loss and nausea.

Eisai Research Laboratories and developed in-house, Lenvima is an orally active tyrosine kinase inhibitor that selectively inhibits the activities of several different molecules including VEGFR, EGFR, PDGFR, and RET. In particular, the agent simultaneously inhibits VEGFR, which is centrally involved in tumor angiogenesis and proliferation of thyroid cancer. This mechanism of action was confirmed through X-ray co-crystal structural analysis to demonstrate a high affinity binding to VEGFR2, and exhibits potent inhibition of kinase activity and rapid binding kinetics. Kinetic analysis

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[Notes to editors]

1. About Lenvima (lenvatinib mesylate)

Lenvima, discovered and developed by Eisai, is an orally