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Eisai Co., Ltd.

EMA ACCEPTS EISAI'S REQUEST FOR ACCELERATED ASSESSMENT OF ANTICANCER AGENT LENVATINIB

LEADING TOWARD SUBMISSION FOR APPROVAL IN EUROPE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.K. subsidiary Eisai Europe Ltd. has been granted an accelerated review by the European Medicines Agency (EMA) for its in-house developed anticancer agent lenvatinib mesylate ("lenvatinib") in the treatment of radioiodine-refractory differentiated thyroid cancer.

The EMA's accelerated review procedure is granted for new medicines that are expected to be of major public health interest, particularly from the viewpoint of therapeutic innovation. Currently, Eisai is planning to submit applications for marketing authorization in Europe and the U.S. in the second quarter of fiscal 2014. In addition, the first application for marketing authorization of lenvatinib in the world was submitted in Japan in June 2014.

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 receptors (VEGFR), in addition to other proangiogenic and oncogenic pathway-related RTKs including fibroblast growth factor receptors (FGFR), the platelet-derived growth factor (PDGF) receptor PDGFRα, KIT and RET that are involved in tumor proliferation. This potentially makes lenvatinib a first-in-class treatment, especially given that it simultaneously inhibits the kinase activities of FGFR as well as VEGFR. It was granted Orphan Drug Designation for thyroid cancer by the health authorities in Japan, Europe and the U.S.

In Europe alone, over 50,000 cases of thyroid cancer were diagnosed in 2012. Although treatment is possible for most types of thyroid cancer, there remains an unmet need for treatment options once the disease has progressed.

Eisai is committed to exploring the potential clinical benefits of lenvatinib in order to further contribute to patients with cancer and their families.

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