## U.S. FDA APPROVES ANTICANCER AGENT LENVIMA<sup>™</sup> (LENVATINIB MESYLATE) AS TREATMENT FOR RADIOACTIVE IODINE-REFRACTORY DIFFERENTIATED THYROID CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has received approval of its in-house developed novel anticancer agent Lenvima<sup>TM</sup> (lenvatinib mesylate) as a treatment for locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (RAI-R DTC) from the U.S. Food and Drug Administration (FDA). Lenvima was granted priority review status by the FDA, and was ultimately approved six months from the submission of the New Drug Application in August 2014, two months ahead of the FDA priority review action date. This marks the first country in the world where the agent has received marketing authorization.

Lenvima

## [Notes to editors]

## 1. About Lenvima (lenvatinib mesylate)

Lenvima, discovered and developed by Eisai, is an orally administered multiple receptor tyrosine kinase (RTK) inhibitor with a novel binding mode that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors (VEGFR1 (FLT1), VEGFR2 (KDR) and VEGFR3 (FLT4)), in addition to other proangiogenic and oncogenic pathway-related RTKs (including fibroblast growth factor (FGF) receptors FGFR1, 2, 3 and 4; the platelet-derived growth factor (PDGF) receptor PDGFR ; KIT; and RET) involved in tumor proliferation. In particular, the agent simultaneously inhibits VEGFR, FGFR and also RET which are especially involved in tumor angiogenesis and proliferation of thyroid cancer. Furthermore,