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[Notes to editors]

1. About lenvatinib mesylate (generic name, “lenvatinib”)

Discovered and developed in-house, lenvatinib 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, VEGFR2 and VEGFR3) and fibroblast growth factor (FGF) receptors (FGFR1, FGFR2, FGFR3 and FGFR4) in addition to other proangiogenic and oncogenic pathway-related RTKs (including the platelet-derived growth factor (PDGF) receptor PDGFRα; KIT; and RET) involved in tumor proliferation.

Currently, Eisai has obtained license for lenvatinib as a treatment for refractory thyroid cancer in over 45 countries including in the United States, Japan, in Europe, Korea, Canada, and Mexico, and has submitted applications for regulatory review in countries throughout the world including South Africa and Malaysia. Specifically, Eisai has obtained license for the agent indicated in the United States for treatment for locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, in Japan for the treatment of unresectable thyroid cancer, and in Europe for the treatment of adult patients with progressive, locally advanced or metastatic differentiated (papillary, follicular, Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine, respectively.

Furthermore, lenvatinib was also licensed in the United States in May 2016 for an additional indication in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy.

Meanwhile, Eisai is conducting clinical studies of lenvatinib in several other tumor types such as hepatocellular carcinoma (Phase III), endometrial carcinoma (Phase II), biliary tract cancer (Phase II), and in combination with an immune checkpoint inhibitor for various types of cancer (Phase Ib/II).

Lenvatinib is marketed globally for use in the treatment of thyroid cancer and also in the United States for use in the treatment of renal cell carcinoma under the brand name Lenvima. Lenvatinib has been designated as an orphan drug for thyroid cancer by the regulatory authorities in Japan, the United States and Europe. Under European regulations, any licensed medicine that previously received orphan drug designation for an indication and now received license for a non-orphan indication must be marketed under a different trade name. As such, lenvatinib will be marketed as Kisplyx® ▼ in the European Union for the indication covering renal cell carcinoma.

2. About the Phase II Clinical Study (Study 205)[1]

Study 205 was a multicenter, randomized, open-label study of the combination of lenvatinib (18 mg) plus everolimus (5 mg), lenvatinib alone (24 mg), and everolimus alone (10 mg) in patients with unresectable advanced or metastatic renal cell carcinoma following one prior VEGF-