EISAI TO INITIATE PHASE III CLINICAL STUDY OF ANTICANCER AGENT LENVATINIB AS POTENTIAL FIRST-LINE THERAPY FOR ADVANCED RENAL CELL CARCINOMA

SIMULTANEOUS DEVELOPMENT OF TWO COMBINATION THERAPIES LENVATINIB/EVEROLIMUS AND LENVATINIB/PEMBROLIZUMAB

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today the initiation of a global Phase III Clinical Study (Study 307, CLEAR Study) of its in-house developed multiple receptor tyrosine kinase inhibitor lenvatinib mesylate (lenvatinib) in respective combination regimens with the anticancer agent everolimus and the anti-PD-1 antibody pembrolizumab as a potential first-line treatment for advanced renal cell carcinoma.

The CLEAR (Comparison of the efficacy and safety of Lenvatinib in combination with Everolimus or -

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[Notes to editors]

1. About lenvatinib mesylate (lenvatinib , generic name, product names: Lenvima®, Kisplyx®)

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 approval 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 is undergoing regulatory review in countries throughout the world including South Africa and Malaysia. Specifically, Eisai has obtained approval for the agent indicated in the United States for the treatment of 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.

Lenvatinib was also approved 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. Furthermore, lenvatinib was approved in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF) targeted therapy in Europe in August 2016. L

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