FOR IMMEDIATE RELEASE

EISAI AND MERCK & CO., INC., KENILWORTH, N.J., U.S.A. PROVIDE UPDATE ON SUPPLEMENTAL NEW DRUG APPLICATION (sNDA) FOR LENVATINIB IN FIRST-LINE UNRESECTABLE HEPATOCELLULAR CARCINOMA

TOKYO March 25, 2018 – Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside the United States and Canada), announced today that the U.S. Food and Drug Administration (FDA) has extended the action date for the supplemental New Drug Application (sNDA) for the multiple receptor tyrosine kinase inhibitor LENVIMA® (generic name: lenvatinib mesylate) for the potential first-line treatment of patients with unresectable hepatocellular carcinoma (HCC).

The FDA has indicated that the extension of the Prescription Drug User Fee Act (PDUFA) date is needed to allow additional time for review of the application. The agency expects to complete the review on or before August 24, 2018, thus extending the target action date by a standard extension period of three months from the original PDUFA action date of May 24, 2018.
Eisai, as the marketing authorization holder, is working closely with the FDA to support the continued review of this application.

LENVIMA is approved by the U.S. FDA for the treatment of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC). LENVIMA is also approved by the U.S. FDA in combination with everolimus for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy.

Media Inquiries:

Eisai Co., Ltd.
Public Relations Department
+81-(0)3-3817-5120

About LENVIMA (lenvatinib mesylate)

Discovered by Eisai, LENVIMA 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 pathway-related RTKs (including the platelet-derived growth factor (PDGF) receptor PDGFRα; KIT; and RET) involved in tumor angiogenesis, tumor progression and modification of tumor immunity.

Currently, LENVIMA is approved as a treatment for refractory thyroid cancer in over 50 countries, including the United States, Japan, in Europe and Asia. Additionally, Eisai has obtained approval for the agent in combination with everolimus as a treatment for renal cell carcinoma (second-line) in over 40 countries, including the United States and in Europe. In Europe, the agent was launched under the brand name Kisplyx® for renal cell carcinoma.

LENVIMA is approved as a monotherapy for unresectable hepatocellular carcinoma in Japan (March 2018).

Eisai has submitted applications for an indication covering hepatocellular carcinoma in the United States and Europe (July 2017), China (October 2017), Taiwan (December 2017) and other countries.

About the Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. Strategic Collaboration

In March 2018, Eisai and Merck & Co., Inc. Kenilworth N.J., U.S.A., through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of LENVIMA. Under the agreement, the companies will develop and commercialize LENVIMA jointly, both as monotherapy and in combination with Merck & Co., Inc. Kenilworth N.J., U.S.A.'s anti-PD-1 therapy. In addition to ongoing clinical studies of the combination, the companies will jointly initiate new clinical studies evaluating the combination to support 11 potential indications in six types of cancer, as well as a basket trial targeting six additional cancer types. The combination is not approved in any cancer types today.

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