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Phase 3 Trial Shows Lenvatinib Meets Primary Endpoint of Progression Free Survival in Radioiodine-Refractory Differentiated Thyroid Cancer

Woodcliff Lake, NJ, February 2, 2014 – Eisai Inc. announced today that the Phase 3 SELECT trial (Study 303) of investigational agent lenvatinib met its primary endpoint. Compared to placebo, lenvatinib showed a highly statistically significant improvement in progression free survival (PFS) in patients with radioiodine-refractory differentiated thyroid cancer (RR-DTC). The preliminary safety analyses showed that the five most common adverse reactions were hypertension, diarrhea, decreased appetite, decreased weight, and nausea. Based on these clinical results, Eisai will submit marketing authorization applications for lenvatinib to health authorities in the United States, Japan, and Europe.

The SELECT (**S**tudy of **E**7080 **LE**nvatinib in Differentiated **C**ancer of the **T**hyroid) study was a multicenter, randomized, double-blind, placebo-controlled Phase 3 study to compare the PFS of patients with radioiodine-refractory differentiated thyroid cancer and radiographic evidence of disease progression within the prior 12 months, treated with once-daily, oral lenvatinib (24mg) versus placebo. Secondary endpoints of the study included overall response rate (ORR), overall survival (OS), and safety. The study enrolled 392 patients at over 100 sites in Europe, North and South America and Asia and was conducted by Eisai in collaboration with the SFJ Pharmaceuticals Group.

“These results show the potential role of the investigational drug lenvatinib in this rare, hard-to-treat cancer,” said Kenichi Nomoto, PhD, President, Oncology Product Creation Unit, Eisai Product Creation Systems. “RR-DTC remains an unmet need with a limited number of treatment options.”

Lenvatinib, discovered and developed by Eisai, was granted Orphan Drug Designation (ODD) in Japan for thyroid cancer in August 2012; in the United States for follicular, medullary, anaplastic, and metastatic or locally advanced papillary thyroid cancer in December 2012; and in Europe for follicular and papillary thyroid cancer in April 2013.

Eisai’s ongoing global clinical trial program includes Phase 3 and Phase 2 studies in several other tumor types. Eisai is committed to the therapeutic area of oncology and to understanding the potential clinical benefits of lenvatinib in order to further contribute to patients and their families.

About Lenvatinib (E7080)
Lenvatinib is an oral inhibitor of select receptor tyrosine kinases (RTKs), including VEGFR 1-3, FGFR 1-4, PDGFR-β, KIT and RET involved in angiogenesis and tumor proliferation. It is currently under investigation as a potential treatment for thyroid, hepatocellular, endometrial and other solid tumor types.

About Thyroid Cancer
Thyroid cancer is the most common endocrine malignancy and global figures show that its incidence has increased significantly over the last 50 years. In the United States, rates for new thyroid cancer cases have been rising 6.4 percent each year over the past 10 years, with approximately 60,220 new cases in 2013. Differentiated thyroid cancer accounts for approximately 90 percent of all thyroid cancers.

About Eisai Inc.
At Eisai Inc., *human health care* is our goal. We give our first thoughts to patients and their families, and helping to increase the benefits health care provides. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., we have a passionate commitment to patient care that is the driving force behind our efforts to help address unmet medical needs. We are a fully integrated pharmaceutical business with discovery, clinical, manufacturing and marketing capabilities. Our key areas of commercial focus include oncology and specialty care (Alzheimer's disease, epilepsy and metabolic disorders). To learn more about Eisai Inc., please visit us at www.eisai.com/US.

Eisai Inc. has affiliates that are part of a global product creation organization that includes R&D facilities in Massachusetts, New Jersey, North Carolina and Pennsylvania, as well as a global demand chain organization that includes manufacturing facilities in Maryland and North Carolina. Eisai's global areas of R&D focus include neuroscience; oncology; metabolic disorders; vascular, inflammatory and immunological reaction; and antibody-based programs.

About Eisai Co., Ltd.
Eisai Co., Ltd. is a research-based *human health care* (*hhc*) company that discovers, develops and markets products across the world through a global network of research facilities, manufacturing sites and marketing subsidiaries. For more information about Eisai's global operations, please visit www.eisai.com.

About the SFJ Pharmaceuticals Group
The SFJ Pharmaceuticals Group, which includes SFJ Pharma Ltd., is a global drug development company that provides a unique co-development partnering model for some of the world's top pharmaceutical and biotechnology companies. SFJ uses its financial strength and core team of pharmaceutical development experts to provide highly customized partnering models in which SFJ provides the funding and clinical development supervision, necessary to obtain regulatory approval for some of the most promising drug development programs of pharmaceutical and biotechnology companies.

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