PHASE III TRIAL SHOWS LENVATINIB MEETS PRIMARY ENDPOINT OF PROGRESSION FREE SURVIVAL BENEFIT IN TREATMENT OF RADIOIODINE-REFRACTORY DIFFERENTIATED THYROID CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that the Phase III SELECT trial (Study 303) of lenvatinib, an investigational selective tyrosine kinase inhibitor (TKI) with a novel binding mode, the first-in-class of its kind, 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 SELECT (Study of (E7080) LEnvatinib in differentiated Cancer of the Thyroid) study was a multicenter, randomized, double-blind, placebo-controlled Phase III study to compare the PFS of patients with RR-DTC and radiographic evidence of disease progression within the prior 12 months, treated with once-daily, oral lenvatinib (24 mg) 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. The preliminary safety analysis 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 Japan, the United States and Europe. If approved, lenvatinib will be the first molecular-targeted small molecule agent developed by a Japanese pharmaceutical company.

Thyroid cancer is the most common endocrine malignancy and global figures show that its incidence has significantly increased over the last 50 years. RR-DTC, a life-threatening form of the disease, has a significant unmet treatment need. Lenvatinib, discovered and developed by Eisai, was granted Orphan Drug Designation (ODD) in Japan, the United States and Europe.

Eisai has also initiated a global Phase III trial of lenvatinib in hepatocellular carcinoma (HCC) and is conducting Phase II studies of lenvatinib in several other tumor types. Eisai is committed to understanding the potential clinical benefits of lenvatinib in order to further contribute to patients with cancer, including patients with thw[(p) Eurc-.0003.48asdenA h thnbut3.7(tienittere)5.patie1.39 lenvatin59nvatinT.taST.taST.o,44a

[Notes to editors]

1. About Lenvatinib (E7080)

Lenvatinib, discovered and developed by Eisai, is an orally active, selective inhibitor of receptor tyrosine kinases (RTKs) with a novel binding mode, including KDR (VEGFR-2), Flt-1 (VEGFR-1), RET, FGFR1, PDGFR-β and c-kit, involved in angiogenesis and tumor proliferation. It is currently under development as a potential treatment for thyroid, hepatocellular (Phase III), endometrial (Phase II) and other solid tumor types. Lenvatinib 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.

2. About Thyroid Cancer

Thyroid cancer refers to cancer that forms in the tissues of the thyroid gland, located at the base of the throat near the trachea. It is more common in women than in men and usually occurs between the ages of 25 and 65. The most common types of thyroid cancer, papillary and follicular (including Hürthle cell), are classified as differentiated thyroid cancer and account for approximately 95% of all cases. The remaining cases are classified as either undifferentiated (3-5% of cases) and medullary carcinoma (1-2% of cases). While most differentiated thyroid cancer patients are curable with surgery and radioactive iodine treatment, a small percentage of patients do not respond to therapy. There are limited treatment options for this difficult-to-treat, life-threatening and treatment-refractory form of thyroid cancer.

3. About the SFJ Pharmaceuticals Group

The SFJ Pharmaceuticals Group, which includes SFJ Pharma Ltd., is a Global Drug Development Company, which 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.