News Release

Contacts:

Media
Laurie Landau
Eisai Inc.
201-746-2510

Investors
Alex Scott
Eisai Inc.
201-746-2177

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U.S. FDA Grants Eisai's Investigational Agent Lenvatinib Priority Review Designation for the Treatment of Advanced Thyroid Cancer

Woodcliff Lake, NJ, October 14, 2014 – Eisai Inc. announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for its in-house developed agent lenvatinib mesylate (lenvatinib) as a treatment for progressive radioactive iodine-refractory differentiated thyroid cancer (RAI-refractory DTC) and granted the NDA Priority Review status.

Priority Review designation occurs when the FDA believes the drug has the potential to provide "a significant improvement in safety or effectiveness of the treatment, prevention or diagnosis of a serious condition."

Lenvatinib, discovered and developed by Eisai, is an oral multiple receptor tyrosine kinase inhibitor with a unique binding mode that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors, in addition to other proangiogenic and oncogenic pathway-related tyrosine kinases thought to be involved in tumor proliferation.

Thyroid cancer is the most common endocrine malignancy and global figures show that its incidence has significantly increased over the last 50 years. The number of patients newly diagnosed with thyroid cancer in 2014 in the U.S. is estimated to be approximately 62,980.

Although treatment is possible for most types of thyroid cancer, once the disease has progressed to RAI-refractory DTC, treatment options are limited and there remains a significant unmet medical need.

About Lenvatinib

Lenvatinib, discovered and developed by Eisai, is an oral multiple receptor tyrosine kinase inhibitor with a unique binding mode that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors (VEGFR1 (FLT1), VEGFR2 (KDR) and VEGFR3 (FLT4)), in addition to other proangiogenic and oncogenic pathway-related tyrosine kinases. These include fibroblast growth factor receptors (FGFR), the platelet-derived growth factor (PDGF) receptor PDGFRα, KIT and RET, which are thought to be involved in tumor proliferation.[1] Eisai was granted Orphan Drug Designation (ODD) for lenvatinib in various types of thyroid cancer in the United States, Japan, and Europe. It is currently under investigation in thyroid, hepatocellular, endometrial, non-small cell lung cancer, and other solid tumor types.

About the SELECT Trial
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 progression-free survival of patients with RAI-refractory DTC and radiographic evidence of disease progression within the prior 12 months, treated with once-daily, oral lenvatinib (24 mg) versus placebo. The study enrolled 392 patients in 117 sites in Europe, North and South America and Asia and was conducted by Eisai in collaboration with the SFJ Pharmaceuticals Group.

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 most are in their 40s or 50s at time of diagnosis. Thyroid cancer is the most common endocrine malignancy and global figures show that its incidence has increased significantly over the last 50 years.

The most common types of thyroid cancer, papillary and follicular (including Hurthle cell), are classified as differentiated thyroid cancer (DTC) and account for approximately 90% of all cases. The remaining cases are classified as either medullary (5-7% of cases) or anaplastic (1-2% of cases). While most DTC patients are curable with surgery and radioactive iodine treatment, the prognosis for those patients whose cancers persist or recur is poor. There are limited treatment options for radioactive iodine-refractory DTC.

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 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.