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Eisai Co., Ltd.

EISAI RECEIVES ORPHAN DRUG DESIGNATION FOR ANTICANCER AGENT LENVATINIB IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has received orphan drug designation from Japan's Ministry of Labour, Health and Welfare for its multikinase inhibitor lenvatinib mesylate ("lenvatinib") for the treatment of thyroid cancer, the drug's prospective indication.

Lenvatinib, discovered and being developed in-house, is an anti-angiogenic agent with a unique inhibitory profile against the receptor tyrosine kinase family of kinases. It is a potent inhibitor of the VEGF (Vascular Endothelial Growth Factor) receptor, VEGFR2, RET (Rearranged During Transfection), and a number of other types of kinases involved in angiogenesis and tumor proliferation. Based on the results of clinical studies conducted thus far, lenvatinib is expected to be effective in the treatment of patients with thyroid cancer.

Thyroid cancer constitutes an area with significant unmet medical needs due to the limited treatment options available for patients with advanced stages of the disease. To address this issue, Eisai is currently conducting Phase III studies with lenvatinib in patients with radioiodine-refractory differentiated thyroid cancer (DTC) as part of a global development program that encompasses the United States, Europe, Japan and other parts of Asia, with the aim of submitting marketing authorization applications for the agent before the end of fiscal 2013. Furthermore, Eisai is also conducting Phase II studies investigating the potential of the agent as a treatment for endometrial cancer, melanoma, glioma and non-small cell lung cancer, primarily in the United States and Europe, in addition to a PhaseI/II study in hepatocellular carcinoma (HCC) in Japan and Asia.

Eisai defines oncology as a therapeutic area of focus, and has already received orphan drug designation for a number of anticancer agents currently under development. Halaven, a novel anticancer agent discovered and being developed in-house, has been designated as an orphan drug for soft-tissue sarcoma by the U.S. Food and Drug Administration (FDA), while the folate receptor alpha monoclonal antibody farletuzumab has been designated as an orphan drug for ovarian cancer by both the FDA and the European Commission (EC). Eisai remains committed to bringing innovative new drugs to market as early as possible, and to making further contributions to address the significant unmet medical needs of cancer patients and their families.

[Please refer to the following notes for further information on thyroid cancer, the Orphan Drug Designation System in Japan and RET]

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[Notes to editors]

1. Thyroid Cancer

Thyroid cancer refers to cancer that forms in the tissues of the thyroid gland, located at the base of the throat or near the trachea. It affects more women than men and usually occurs between the ages of 25 and 65. The most common types of thyroid cancer, papillary and follicular (including Hurthle Cell), are classified as differentiated thyroid cancer and account for 95 percent 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 do not respond to therapy.

2. Orphan Drug Designation System in Japan

Japan's orphan drug designation system aims to support the development of drugs for diseases that, despite there being a significant medical need for treatments, affect only a small number of patients, and for which research and development is virtually nonexistent. As stipulated in Article 77-2 of the Pharmaceutical Affairs Law of Japan, a drug must meet the following conditions in order to be considered for orphan drug designation in Japan: the drug should be used to treat a disease that affects less than 50,000 people in Japan; the drug treats a disease or condition for which there are no other treatments available in Japan, or the proposed drug is clinically superior to drugs already available on the Japanese market; and the applicant should have a clear product development plan and scientific rationale to support the necessity of the drug in Japan. Specific measures to support the development of orphan drugs include prioritized consultation regarding clinical development and priority review of applications, reduced application fees, extended registration validity period, financial assistance to help cover research and development expenditures, and tax incentives.

3. RET (Rearranged During Transfection)

RET is a cancer-causing gene that encodes receptor-type tyrosine kinase, and is reportedly responsible for gene mutations in some types of thyroid cancer. RET tyrosine kinase inhibitors have been confirmed to have an inhibitory effect on tumor formation by inhibiting the hyperactivity of mutated RET kinase in these certain types of thyroid cancer. Recent research has also revealed that RET and KIF5B gene fusion (gene mutation) occurs in some lung cancer patients, which means that RET tyrosine kinase inhibitors may potentially be used in the treatment of lung cancer patients with this gene mutation.