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CFDA accepts Eisai's NDA for cancer drug

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Eisai Co., Ltd. announced that the China Food and Drug Administration (CFDA) has accepted for review a New Drug Application (NDA) submitted for Eisai's in-house discovered and developed anticancer agent lenvatinib mesylate (product names: Lenvima / Kisplyx, "lenvatinib") for use in the treatment of hepatocellular carcinoma (HCC) in China.

The NDA was based on the results of the REFLECT study (Study 304), a multicenter, open-label, randomized, global Phase III trial comparing the efficacy and safety of lenvatinib versus sorafenib, a standard treatment for HCC, as a first-line treatment for the patients with unresectable HCC.

In the REFLECT study, lenvatinib demonstrated a treatment effect on the primary endpoint of Overall Survival (OS) by the statistical confirmation of non-inferiority to sorafenib. Additionally, lenvatinib showed highly statistically significant and clinically meaningful improvements compared to sorafenib in the secondary endpoints of Progression Free Survival (PFS), Time To Progression (TTP), and Objective Response Rate (ORR). In this study, the five most common adverse events observed in the lenvatinib arm were hypertension, diarrhea, decreased appetite, weight loss and fatigue, which is consistent with the known side-effect profile of lenvatinib.

Liver cancer is the second leading cause of cancer related deaths and is estimated to be responsible for approximately 750,000 deaths per year globally. Additionally, approximately 780,000 cases are newly diagnosed each year, about 80% of which occur in Asian regions. Specifically, in China, there are approximately 395,000 new cases and 380,000 deaths per year, accounting for approximately 50% of cases worldwide.2 HCC accounts for 85% to 90% of primary liver cancer cases. Treatment options for unresectable HCC are limited. Therefore, HCC is extremely difficult to treat, and the development of new treatments is necessary.

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Eisai positions oncology as a key therapeutic area, and is aiming to discover revolutionary new medicines with the potential to cure cancer. Eisai is committed to exploring the potential clinical benefits of lenvatinib as it seeks to contribute further to

addressing the diverse needs of, and increasing the benefits provided to patients with cancer, their families, and healthcare providers.

Discovered and developed in-house, lenvatinib 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 proangiogenic and oncogenic pathway-related RTKs (including the platelet-derived growth factor (PDGF) receptor PDGFRalpha; KIT; and RET) involved in tumor proliferation. Currently, Eisai has obtained approval for lenvatinib as a treatment for refractory thyroid cancer in over 50 countries, including the United States, Japan, and in Europe, under the brand name Lenvima.

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. A Phase III study of lenvatinib in separate combinations with everolimus and pembrolizumab in renal cell carcinoma (first-line) is underway. A Phase Ib/II study to investigate the agent in combination with pembrolizumab in select solid tumors (endometrial cancer, non-small cell lung cancer, renal cell carcinoma, urothelial cancer, head and neck cancer, and melanoma) and a Phase Ib study in HCC are also underway. Additionally, a Phase Ib study to investigate the agent in combination with nivolumab in HCC are initiated in Japan.