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Eisai Co., Ltd.

U.K. NICE RECOMMENDS ANTICANCER AGENT LENVIMA® AS TREATMENT FOR THYROID CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its in-house developed anticancer agent Lenvima® (lenvatinib mesylate, "lenvatinib") has been recommended by the U.K. National Institute for Health and Clinical Excellence (NICE) as a treatment for progressive, locally advanced or metastatic differentiated thyroid cancer (papillary, follicular or Hürthle cell) in adults whose disease does not respond to radioactive iodine, in NICE's Final Appraisal Determination (FAD).[1]
Following the issue of the FAD by NICE, lenvatinib will be eligible for reimbursement for this indication via the National Health Service in England (NHS England).

The Appraisal Committee considered that lenvatinib demonstrated a statistically significant improvement in progression free survival and offers an extension in overall survival compared to placebo, respectively. The committee concluded that lenvatinib is one of the few treatment options for progressive, locally advanced or metastatic differentiated thyroid cancer after surgery and radioactive iodine.

Lenvatinib was approved in Europe in May 2015 as a treatment for adults with progressive, locally advanced or metastatic differentiated thyroid cancer (papillary, follicular or Hürthle cell), refractory to radioactive iodine. The agent was launched in the U.K. in June 2015. Furthermore, lenvatinib was approved in September 2016 for an expanded indication in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma following one prior vascular endothelial growth factor (VEGF) targeted therapy, and lenvatinib is marketed under the product name Kisplyx® for this indication. Lenvatinib plus everolimus was recommended by NICE as an option for treating advanced renal cell carcinoma in adults who have had one previous VEGF-targeted therapy in December 2017.

Eisai regards oncology as a key therapeutic area and is aiming to discover revolutionary new medicines with the potential to cure cancer. Eisai remains committed to providing further clinical evidence and expanding patient access for lenvatinib, and by maximizing the value of the drug, seeks to contribute further to addressing the diverse needs of, and increasing the benefits provided to, patients with cancer, their families, and healthcare providers.

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[Notes to editors]

1. About lenvatinib mesylate (product name: Lenvima / Kisplyx, "lenvatinib")

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 PDGFRα; 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, in Europe and Asia, under the brand name Lenvima. Additionally, Eisai has obtained approval for lenvatinib 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.

Furthermore, in a Phase III clinical study (REFLECT Study / Study 304) comparing safety and efficacy of the agent versus sorafenib for the treatment of hepatocellular carcinoma, lenvatinib achieved its primary endpoint of overall survival, meeting the statistical criteria for non-inferiority to sorafenib. Eisai has submitted applications for an indication covering hepatocellular carcinoma in Japan (June 2017), the United States and Europe (July 2017), China (October 2017), Taiwan (December 2017) and other countries.

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 lenvatinib in combination with pembrolizumab in select solid tumors (endometrial cancer, renal cell carcinoma, non-small cell lung cancer, 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 lenvatinib in combination with nivolumab in HCC has been initiated in Japan.

2. About NICE's New Approach to the Appraisal and Funding of Cancer Drugs

The former Cancer Drugs Fund (CDF) was established in 2009 as a means to improve patients' access to new cancer drugs including those which were "Not Recommended" by NICE. These drugs would be evaluated and listed in the CDF with their costs reimbursed through the fund. However, due to a severe increase in financial burden, a new scheme for NICE appraisal and funding of cancer drugs, including a new CDF, came into operation on July 29, 2016. All novel cancer drugs that had been newly approved would undergo NICE appraisal while cancer drugs that were listed in the former CDF would be eligible for reappraisal by NICE under the new scheme depending on the judgment of each company. The NICE appraisal process consists initially of an Appraisal Consultation Document, the issue of a Final Appraisal Determination, and ultimately the setting of Final Guidance. While cancer drugs that are "Recommended" are eligible for reimbursement through the NHS England, drugs that are "Not Recommended" require an Individual Funding Request (IFR) to be deliberated on a case-by-case basis, and therefore their use is greatly limited. Cancer drugs that could possibly be recommended but are judged to lack sufficient evidence can be given a "Limited Recommendation under the CDF", with provisional access secured under the CDF for a maximum of two years. After receiving this designation, NICE conducts a reappraisal based on the new evidence, and ultimately determines whether to either "Recommend" or "Not Recommend" the drug.

[1] "Alternative treatments for people with thyroid cancer to be offered routinely on the NHS, says NICE" https://www.nice.org.uk/news, accessed: February 15, 2018