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Eisai receives license for new indication for anticancer agent Kisplyx

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TOKYO: Eisai Co., Ltd. announced that its European regional headquarters Eisai Europe Ltd. has received license from the European Commission for anticancer agent Kisplyx (generic name: lenvatinib mesylate, "lenvatinib") 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. Following the United States, Europe marks the second region where lenvatinib has been licensed for the advanced renal cell carcinoma indication.

This license was based on a Phase II clinical study that evaluated the safety and efficacy of lenvatinib in combination with everolimus in patients with unresectable advanced or metastatic renal cell carcinoma following one prior VEGF-targeted therapy. From the results of the study, the lenvatinib plus everolimus group demonstrated a significant extension in the study's primary endpoint of progression free survival (PFS) compared to the everolimus alone group.

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The number of patients with renal cancer is estimated to be approximately 338,000 worldwide, including approximately 115,000 in Europe, 58,000 in the United States and 17,000 in Japan.Renal cell carcinoma comprises more than 90% of all malignancies of the kidney, and originates from malignant cells in the lining of the tubules of the kidney. The incidence of renal cell carcinoma in people over 55 years of age is rising, and it is more likely to affect men than women. For advanced or metastatic renal cell carcinoma that is difficult to treat with surgery, the standard treatment is molecular targeted drug therapy,

however with low 5-year survival rates, this remains a disease with significant unmet medical need.

In Europe, lenvatinib has been designated as an orphan drug for thyroid cancer and is marketed as Lenvima for this indication. In Europe, renal cell carcinoma does not meet the criteria for orphan drug designation. Accordingly, under European regulations, any licensed medicine that previously received orphan drug designation for an indication and subsequently receives license for a non-orphan indication must be marketed under a different trade name. As such, lenvatinib will be marketed as Kisplyx in the European Union for the indication covering renal cell carcinoma.
Eisai positions 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 for lenvatinib aimed at maximizing value of the drug 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.