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Eisai receives positive CHMP opinion on new indication for anticancer agent

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Singapore: Eisai Co., Ltd. announced that its European regional headquarters Eisai Europe Ltd. has received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) on anticancer agent lenvatinib mesylate in combination with everolimus. It's for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF) targeted therapy. If approved, lenvatinib will be launched under the brand name Kisplyx for this indication.

The CHMP's positive opinion was based on a Phase II clinical study (Study 205)(1) 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 group who received the combination of lenvatinib plus everolimus demonstrated a significant extension in progression free survival, the study's primary endpoint, as well as a higher objective response rate compared to the everolimus alone group. The most common treatment-emergent adverse events (TEAEs) reported in the lenvatinib plus everolimus group were diarrhea, decreased appetite and fatigue. The most common TEAEs of Grade 3 or higher were diarrhea, hypertension and fatigue.

The number of patients with renal cancer in Europe is estimated to be 115,000,2 and renal cell carcinoma comprises more than 90% of all malignancies of the kidney.3 For advanced or metastatic renal cell carcinoma that is difficult to treat with surgery, the standard treatment method is molecular targeted drug therapy, however with low 5-year survival rates, this

remains a disease with significant unmet medical need.

Currently lenvatinib has been launched in countries including the United States, Japan and in Europe under the product name Lenvima as a treatment for refractory thyroid cancer. Furthermore, in May 2016, lenvatinib was approved in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior VEGF-targeted therapy by the U.S. Food and Drug Administration in the United States.