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Tokyo: Japan's pharma giant Eisai Co Ltd announced that its European regional headquarters Eisai Europe Ltd has submitted a new application to the European Medicines Agency (EMA) for its in-house developed novel anticancer agent lenvatinib mesylate (for use in the treatment of advanced or metastatic renal cell carcinoma).

As a new medicine that is expected to be of major public health interest, particularly from the viewpoint of therapeutic innovation, lenvatinib has been granted an accelerated review by the EMA.

The number of patients with renal cancer in Europe is estimated to be 115,000 and renal cell carcinoma comprises more than 90% of all malignancies of the kidney. 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.

This application was based on a Phase II clinical study (Study 205)3 which compared the efficacy and safety among three groups including a combination of lenvatinib (18 mg) plus everolimus (5 mg), lenvatinib alone (24 mg) and everolimus alone (10 mg) in unresectable advanced or metastatic renal cell carcinoma following one prior vascular endothelial growth factor targeted therapy.

From the results of the study, the combination of lenvatinib plus everolimus group demonstrated a significant extension in progression free survival (PFS), the study's primary endpoint, compared to the everolimus alone group. Additionally, the lenvatinib alone group demonstrated an extension in PFS compared to the everolimus alone.

Both the lenvatinib plus everolimus group and the lenvatinib alone group showed an improvement in 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.

Currently lenvatinib has been launched in the United States, Japan and Europe under the product name Lenvima as a treatment for refractory thyroid cancer. In addition, lenvatinib has received a breakthrough therapy designation from the US Food and Drug Administration for the potential indication of advanced and/or metastatic renal cell carcinoma, and an application seeking approval for an indication covering advanced or metastatic renal cell carcinoma was submitted in the United States in November 2015.

Eisai intends to discuss further steps regarding potential submission strategies for this indication with the regulatory authorities in Japan as well. Eisai is committed to exploring the potential clinical benefits of lenvatinib in order to further contribute to patients with cancer and their families.