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Japan's Eisai Co Ltd has announced that its US subsidiary Eisai Inc. has received approval from the US Food and Drug Administration (FDA) for an additional indication for Eisai's in-house developed novel anticancer agent Lenvima (lenvatinib mesylate) in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy.

This is the only combination regimen to significantly prolong progression-free survival (PFS) when compared with a standard of care in patients with advanced renal cell carcinoma following prior anti-angiogenic therapy. Lenvima was designated as a Breakthrough Therapy by the FDA and also received a Priority Review, with approval obtained approximately six months after application submission.

The approval was based on a Phase II clinical study (Study 205)1 that compared the safety and efficacy of Lenvima alone, and in combination with everolimus, in patients with unresectable advanced or metastatic renal cell carcinoma following one prior vascular endothelial growth factor-targeted therapy.

From the results of the study, the group who received the combination of Lenvima plus everolimus demonstrated a significant extension in PFS, 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.

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