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Eisai, Merck get FDA approval for LENVIMA capsules to treat HCC

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Marks second approval under Eisai-Merck global collaboration to co-develop and co-commercialize LENVIMA, following Japan in March 2018



Eisai Inc. and Merck known as MSD outside of the United States and Canada, announced the U.S. Food and Drug Administration (FDA) approved the kinase inhibitor LENVIMA® (lenvatinib) for the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC).

This approval was based on results from REFLECT (Study 304), where LENVIMA demonstrated a proven treatment effect on overall survival (OS) by statistical confirmation of non-inferiority, as well as statistically significant superiority and clinically meaningful improvements in progression-free survival (PFS) and objective response rate (ORR) when compared with sorafenib in patients with previously untreated unresectable HCC.

"Eisai strives to be a leading global R&D-based pharmaceutical company, driven by our human health care (hhc) mission to improve the lives of patients and their loved ones," said Shaji Procida, President and Chief Operating Officer, Eisai Inc., and Commercial Head of the Oncology Business Group, Americas at Eisai. "That purpose is what has propelled us toward this win for patients with unresectable hepatocellular carcinoma. Our goal is to bring monumental solutions to patients and health care providers, changing expectations for the oncology landscape, and we look forward to continuing this work in our ongoing collaboration with Merck."

Under the collaboration, Eisai and Merck initiated co-commercialization activities for LENVIMA in the U.S. in June 2018. Since the initial launch, more than 10,000 patients were treated with LENVIMA, which is approved in more than 50 countries worldwide.