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Eisai, Merck provide Update on sNDA for Lenvatinib

25 May 2018 | News

LENVIMA is approved as a monotherapy for unresectable hepatocellular carcinoma in Japan (March 2018)

Eisai Inc. and Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced that the U.S. Food and Drug Administration (FDA) has extended the action date for the supplemental New Drug Application (sNDA) for lenvatinib for the potential first-line treatment of patients with unresectable hepatocellular carcinoma (HCC).

The FDA has indicated that the extension of the Prescription Drug User Fee Act (PDUFA) date is needed to allow additional time for review of the application. The agency expects to complete the review on or before August 24, 2018, thus extending the target action date by a standard extension period of three months from the original PDUFA action date of May 24, 2018.

Eisai, as the marketing authorization holder, is working closely with the FDA to support the continued review of this application.

Lenvatinib (available as LENVIMA®) is approved by the U.S. FDA for the treatment of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer.

Lenvatinib is also approved by the U.S. FDA in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy.