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Eisai, Merck receive breakthrough therapy designation from FDA

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For LENVIMA (lenvatinib) plus KEYTRUDA (pembrolizumab) Combination Treatment as Potential First-Line Treatment of Patients with Advanced Unresectable Hepatocellular Carcinoma Not Amenable to Locoregional Treatment

Japanese pharmaceutical firm Eisai, and Merck & Co., Inc., Kenilworth, N.J., U.S.A., known as MSD outside the United States and Canada, have announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for LENVIMA, the orally available kinase inhibitor discovered by Eisai, in combination with KEYTRUDA, Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s anti-PD-1 therapy, for the potential first-line treatment of patients with advanced unresectable hepatocellular carcinoma (HCC) not amenable to locoregional treatment.

This is the third Breakthrough Therapy designation for the LENVIMA plus KEYTRUDA combination. The first two Breakthrough Therapy designations for the combination were in advanced and/or metastatic renal cell carcinoma and advanced and/or metastatic non-microsatellite instability-high (MSI- H)/proficient mismatch repair (pMMR) endometrial carcinoma, received in January 2018 and July 2018, respectively.

The Breakthrough Therapy designation is an FDA program intended to expedite development and review of medicines for serious or life-threatening conditions. In order to qualify for this designation, preliminary clinical evidence must demonstrate that the therapy may provide substantial improvement over currently available therapy on at least one clinically significant endpoint.

This Breakthrough Therapy designation is based on interim results from the Phase 1b trial KEYNOTE-524/Study 116. An earlier interim analysis was presented at the 2019 American Association for Cancer Research (AACR) Annual Meeting.

The combination of LENVIMA plus KEYTRUDA is investigational. The efficacy and safety of this combination has not been established. The LENVIMA plus KEYTRUDA combination is not approved in any cancer types today.