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ASIA EDITION

Eisai, Merck gets U.S. FDA breakthrough therapy designation for LENVIMA

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In Combination with KEYTRUDA as Therapy for Previously Treated Patients with Advanced and/or Metastatic non-MSI-H/pMMR Endometrial Carcinoma

Eisai Co., Ltd. and Merck & Co., Inc. announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for LENVIMA (generic name: lenvatinib mesylate), the orally available kinase inhibitor discovered by Eisai, in combination with Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s anti-PD-1 therapy KEYTRUDA (generic name: pembrolizumab) for the potential treatment of patients with advanced and/or metastatic non-microsatellite instability high (MSI-H)/proficient mismatch repair (pMMR) endometrial carcinoma (EC) who have progressed following at least one prior systemic therapy.

The LENVIMA/KEYTRUDA combination therapy is being jointly developed by Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. as part of the strategic collaboration announced in March 2018. This is the third Breakthrough Therapy designation for LENVIMA and the second Breakthrough Therapy designation for LENVIMA in combination with KEYTRUDA following the Breakthrough Therapy designation for the combination for advanced and/or metastatic renal cell carcinoma announced in January 2018.

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 drug may provide a substantial improvement over currently available therapy on at least one clinically significant endpoint.

The benefits of this Breakthrough Therapy designation include more intensive guidance on an efficient clinical development program, access to senior FDA managers and experienced FDA staff to help accelerate review time, as well as eligibility for rolling review and potentially priority review.

This Breakthrough Therapy designation was based on interim results of the EC cohort in Study 111/KEYNOTE-146, which were presented in June 2018 at the 54th American Society of Clinical Oncology (ASCO) Annual Meeting.

Study 111/KEYNOTE-146 is a multi-center, open-label, single-arm Phase 1b/2 basket trial evaluating the efficacy and safety of LENVIMA in combination with KEYTRUDA in patients with selected solid tumors.