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FDA approves combo drug to treat endometrial carcinoma

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Combination treatment of LENVIMA® (lenvatinib) plus KEYTRUDA® is approved for Patients with Advanced Endometrial Carcinoma That Is Not Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Who Have Disease Progression Following Prior Systemic Therapy

Eisai and Merck have announced that the U.S. Food and Drug Administration (FDA) approved the combination of LENVIMA, the orally available kinase inhibitor discovered by Eisai, plus KEYTRUDA, Merck & Co., Inc., Kenilworth, N.J., U.S.A.s anti-PD-1 therapy, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

This marks the first U.S. approval for the combination of LENVIMA plus KEYTRUDA and the first time an anti-PD-1 therapy is approved in combination with a kinase inhibitor for advanced endometrial carcinoma in the U.S. Following submission on June 17, this is an accelerated approval reviewed under the FDAs Real-Time Oncology Review (RTOR) pilot program, which aims to improve the efficiency of the review process for applications to ensure that treatments are available to patients as early as possible. RTOR allows the FDA to review much of the data earlier, before the applicant formally submits the complete application. This accelerated approval is based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

According to the FDA, this review was conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among its international partners. Under this project, the FDA, the Australian Therapeutic Goods Administration (TGA) and Health Canada collaboratively reviewed applications for two oncology drugs, allowing for simultaneous decisions in all three countries.

The approval was based on data from Study 111/KEYNOTE-146, a Phase 2, multi-cohort, multi-center, open-label, single-arm trial that enrolled 108 patients with metastatic endometrial carcinoma that had progressed following at least one prior systemic therapy in any setting.

“Todays approval of the LENVIMA plus KEYTRUDA combination for advanced endometrial carcinoma that has progressed following prior systemic therapy brings the first approved combination treatment to women with this type of cancer whose tumors are not MSI-H or dMMR and who are not candidates for curative surgery or radiation, and this demonstrates the

potential of our collaboration with Eisai," said Dr. Jonathan Cheng, Vice President, Oncology Clinical Research, Merck & Co., Inc., Kenilworth, N.J., U.S.A. Research Laboratories. "Merck & Co., Inc., Kenilworth, N.J., U.S.A. is committed to developing this combination through the LEAP (LEnvatinib And Pembrolizumab) clinical program, which is under active investigation."

"At least 75% of endometrial cancer cases are not microsatellite instability-high or mismatch repair deficient, and these women have been in need of new treatment options," said Dr. Takashi Owa, Vice President, Chief Medicine Creation and Chief Discovery Officer, Oncology Business Group at Eisai. "We are very pleased that the LENVIMA plus KEYTRUDA combination for patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation has been selected for FDA's RTOR pilot program, launched last year, and has been approved approximately three months after the submission. We look forward to providing this combination therapy to women with certain types of advanced endometrial carcinoma."