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Taiwan approves Merck's KEYTRUDA in combination with Eisai's LENVIMA

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KEYTRUDA, in combination with LENVIMA, is indicated for the treatment of patients with advanced endometrial carcinoma

Eisai Co., Ltd. announced that LENVIMA® (generic name: lenvatinib mesylate), the multiple receptor tyrosine kinase inhibitor discovered by Eisai, in combination with Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside the United States and Canada)'s KEYTRUDA® (generic name: pembrolizumab) has been approved in Taiwan for the treatment of patients with advanced endometrial carcinoma who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

The approval is based on results from the pivotal Phase 3 Study 309/KEYNOTE-775 trial. These results were presented at the Society of Gynecologic Oncology (SGO) 2021 Annual Meeting on Women's Cancer in March 2021, and published in the *New England Journal of Medicine* in January 2022.

LENVIMA plus KEYTRUDA was previously approved under accelerated approval process in Taiwan, 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 based on data from the Study 111/KEYNOTE-146 trial. In accordance with accelerated approval regulations, continued approval was contingent upon verification and description of clinical benefit; these accelerated approval requirements have been fulfilled with the data from Study 309/KEYNOTE-775.