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Eisai's Anti Cancer agent Lenvatinib-Pembrolizumab combo receives EMA in Japan

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As a Treatment for Advanced Renal Cell Carcinoma and Advanced Endometrial Carcinoma

Eisai Co., Ltd. announced on March 30, 2021 that the European Medicines Agency (EMA) has confirmed it has accepted for review applications for the use of its in-house discovered multiple receptor tyrosine kinase inhibitor, lenvatinib mesylate (product name: LENVIMA / Kisplyx, "lenvatinib"), in combination with anti-PD-1 therapy pembrolizumab (brand name: KEYTRUDA), developed by Merck & Co., Inc., Kenilworth, N.J., U.S.A., (known as MSD outside the United States and Canada) as a treatment for patients with advanced renal cell carcinoma (RCC) and advanced endometrial carcinoma (EC), respectively.

The application requesting an indication of lenvatinib in combination with pembrolizumab for RCC is based on the results of the pivotal Phase 3 CLEAR study (Study 307/KEYNOTE-581) for the first-line treatment of patients with advanced RCC, which were presented at 2021 Genitourinary Cancers Symposium (ASCO GU), and simultaneously published in the New England Journal of Medicine in February 2021. In this trial, lenvatinib plus pembrolizumab demonstrated statistically significant and clinically meaningful improvements in the primary endpoint of progression-free survival (PFS) as well as key secondary endpoints of overall survival (OS) and objective response rate (ORR) versus sunitinib.

In addition, the application requesting an indication of lenvatinib in combination with pembrolizumab for EC is based on the results of the pivotal Phase 3 Study 309/KEYNOTE-775 for the treatment of patients with advanced endometrial carcinoma, following one prior platinum-based regimen in any setting, which were presented at the Society of Gynecologic Oncology (SGO) 2021 Annual Meeting on Women's Cancer in March 2021. In this trial, lenvatinib plus pembrolizumab demonstrated a statistically significant and clinically meaningful improvement in the primary endpoints of PFS and OS as well as the secondary endpoint of ORR versus chemotherapy (treatment of physician's choice of doxorubicin or paclitaxel).