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FDA approves combination therapy for Advanced Renal Cell Carcinoma (RCC)

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U.S. Food and Drug Administration (FDA) has approved a combination therapy from Eisai and Merck (MSD) namely, LENVIMA, the orally available multiple receptor tyrosine kinase inhibitor (Eisai), plus KEYTRUDA, the anti-PD-1 therapy (Merck & Co., Inc., Kenilworth, N.J., U.S.A.), for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).

The approval is based on results from the pivotal Phase 3 CLEAR (Study 307)/KEYNOTE-581 trial, in which LENVIMA (lenvatinib) plus KEYTRUDA (pembrolizumab) demonstrated statistically significant improvements. For progression-free survival (PFS), LENVIMA plus KEYTRUDA reduced the risk of disease progression or death by 61%.

"This approval is based in part on data demonstrating that LENVIMA plus KEYTRUDA significantly reduced the risk of disease progression or death versus sunitinib," said Dr. Robert Motzer, Jack and Dorothy Byrne Chair in Clinical Oncology, Kidney Cancer Section Head, Genitourinary Oncology Service, Memorial Sloan Kettering Cancer Center.

"This FDA approval reinforces the potential of KEYTRUDA plus LENVIMA, which is now approved for two different types of cancer. In the study, KEYTRUDA plus LENVIMA demonstrated a survival benefit for patients with advanced renal cell carcinoma, supporting the importance of this combination as a new first-line treatment option for these patients," said Dr. Gregory Lubiniecki, Vice President, Oncology Clinical Research, Merck (U.S.A). Research Laboratories.

"The CLEAR/KEYNOTE-581 trial shows treatment with LENVIMA plus KEYTRUDA resulted in superior outcomes across progression-free survival, overall survival and objective response rate versus sunitinib in patients with advanced renal cell carcinoma," said Dr. Takashi Owa, Chief Medicine Creation and Chief Discovery Officer, Oncology Business Group at Eisai.

This approval was reviewed under the FDA's 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.