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EC approves Merck’s KEYTRUDA in combination with Inlyta to treat RCC

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European Approval Based on KEYNOTE-426 Trial Results Demonstrating Significant Improvement in Overall Survival with KEYTRUDA in Combination with Axitinib Compared to Sunitinib

Merck , known as MSD outside the United States and Canada,has announced that the European Commission has approved KEYTRUDA, Merck’s anti-PD-1 therapy, in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma (RCC). This approval includes patients in all IMDC risk groups. It is based on findings from the pivotal Phase 3 KEYNOTE-426 trial, which demonstrated that KEYTRUDA in combination with axitinib reduced the risk of death by 47% compared with sunitinib (HR=0.53 [95% CI, 0.38, 0.74]; p=0.00005) in patients with advanced RCC. The KEYTRUDA with axitinib combination also demonstrated an improvement in progression-free survival (PFS) and objective response rate (ORR) compared with sunitinib.

“Advanced renal cell carcinoma is one of the most lethal types of cancer, with the majority of patients dying within five years of their initial diagnosis,” said Prof. Thomas Powles, lead investigator for KEYNOTE-426 and director of Barts Cancer Centre. “It’s encouraging that we can now offer patients in Europe the KEYTRUDA with axitinib combination as a first-line treatment option.”

The approval allows marketing of the KEYTRUDA combination in all 28 EU member states plus Iceland, Lichtenstein and Norway.

“The European approval of the KEYTRUDA with axitinib combination for the treatment of advanced RCC marks an important milestone in our efforts for patients with this aggressive disease,” said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. “Offering an additional treatment option in the first-line setting is particularly important in patients with advanced RCC and underscores our commitment to develop KEYTRUDA in areas of unmet need.”