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Merck announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA (pembrolizumab)monotherapy, the company's anti-PD-1 (programmed death receptor-1) therapy, at a dose of 2 mg/kg every three weeks, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinumcontaining chemotherapy.

Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA. Under FDA's accelerated approval regulations, this indication for KEYTRUDA is approved based on tumor response rate and durability of response. An improvement in survival or disease-related symptoms has not yet been established.

KEYTRUDA is the first and only anti-PD-1 therapy approved for both squamous and non-squamous metastatic NSCLC. In addition to approving KEYTRUDA for NSCLC, FDA approved the first companion diagnostic that will enable physicians to determine the level of PD-L1 expression in a patient's tumor.

"Today's approval of KEYTRUDA is the result of our deep commitment to bring the benefits of immunotherapy to cancer patients," said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. "Together with scientists and physicians around the world, we endeavor to improve the lives of patients suffering from these grievous illnesses."

"This important news means that we now have a new immunotherapy option to help patients with squamous and non-squamous metastatic non-small cell lung cancer with disease progression on or after platinum-containing chemotherapy and whose tumors express PD-L1. The durability of response with immune checkpoint inhibitors is exciting and has given new options for our patients," said Dr. Naiyer Rizvi, director of thoracic oncology and director of immunotherapeutics, New York Presbyterian Hospital, Columbia University Medical Center, and a principal investigator for the KEYTRUDA lung cancer clinical program. "And, with the approval of the first PD-L1 companion diagnostic, we can identify patients who are more likely to experience benefit from KEYTRUDA."

KEYTRUDA is an immunotherapy that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby helping the immune system do what it is meant to do: help detect and fight cancer cells. KEYTRUDA can also cause the immune system to attack normal organs and tissues.

Clinical trials found that 22% of patients with this type of cancer produced some PD-L1, according to Merck.

Keytruda will cost about $12,500 per month, or $150,000 a year.