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FDA grants accelerated approval for Keytruda to treat patients with advanced NSCLC

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The U.S. Food and Drug Administration today granted accelerated approval for Keytruda (pembrolizumab) to treat patients with advanced (metastatic) non-small cell lung cancer (NSCLC) whose disease has progressed after other treatments and with tumors that express a protein called PD-L1. Keytruda is approved for use with a companion diagnostic, the PD-L1 IHC 22C3 pharmDx test, the first test designed to detect PD-L1 expression in non-small cell lung tumors.

Lung cancer is the leading cause of cancer death in the United States, with an estimated 221,200 new diagnoses and 158,040 deaths in 2015, according to the National Cancer Institute. NSCLC is the most common type of lung cancer."Our growing understanding of underlying molecular pathways and how our immune system interacts with cancer is leading to important advances in medicine," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Today's approval of Keytruda gives physicians the ability to target specific patients who may be most likely to benefit from this drug."

Keytruda works by targeting the cellular pathway known as PD-1/PD-L1 (proteins found on the body's immune cells and some cancer cells). By blocking this pathway, Keytruda may help the body's immune system fight the cancer cells. In 2014, Keytruda was approved to treat patients with advanced melanoma following treatment with ipilimumab, a type of immunotherapy. Another drug, Opdivo (nivolumab), manufactured by Bristol-Meyers Squibb, also targets the PD-1/PD-L1 pathway and was approved to treat squamous non-small cell lung cancer (a certain kind of NSCLC) in 2015.

The safety of Keytruda was studied in 550 patients with advanced NSCLC. The most common side effects of Keytruda included fatigue, decreased appetite, shortness of breath or impaired breathing (dyspnea) and cough. Keytruda also has the potential to cause severe side effects that result from the immune system effect of Keytruda (known as "immune-mediated side effects").

The effectiveness of Keytruda for this use was demonstrated in a subgroup of 61 patients enrolled within a larger multicenter, open-label, multi-part study. The subgroup consisted of patients with advanced NSCLC that progressed following platinum-based chemotherapy or, if appropriate, targeted therapy for certain genetic mutations (ALK or EGFR). This subgroup also had PD-L1 positive tumors based on the results of the 22C3 pharmDx diagnostic test. Study participants received 10 mg/kg of Keytruda every two or three weeks. The major outcome measure was overall response rate (percentage of patients who experienced complete and partial shrinkage of their tumors). Tumors shrank in 41 percent of patients treated with Keytruda and the effect lasted between 2.1 and 9.1 months.

In the 550 study participants with advanced NSCLC, severe immune-mediated side effects occurred involving the lungs, colon and hormone-producing glands. Other uncommon immune-mediated side effects were rash and inflammation of blood vessels (vasculitis). Women who are pregnant or breastfeeding should not take Keytruda because it may cause harm to a developing fetus or newborn baby. Across clinical studies, a disorder in which the body's immune system attacks part of the peripheral nervous system (Guillain-Barre Syndrome) also occurred.

The FDA granted Keytruda breakthrough therapy designation for this indication because Merck demonstrated through preliminary clinical evidence that the drug may offer a substantial improvement over available therapies. The drug also received priority review status, which is granted to drugs that, at the time the application was submitted, have the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition.

Keytruda was approved under the agency's accelerated approval program, which allows the approval of a drug to treat a serious or life-threatening disease based on clinical data showing the drug has an effect on a surrogate endpoint reasonably likely to predict clinical benefit to patients. This program provides earlier patient access to promising new drugs while the company conducts confirmatory clinical trials. An improvement in survival or disease-related symptoms in patients being treated with Keytruda has not yet been established.

Keytruda is marketed by Merck & Co., based in Whitehouse Station, New Jersey and the PD-L1 IHC 22C3 pharmDx

diagnostic test is marketed by Dako North America Inc. in Carpinteria, California.

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