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FDA approves Opdivo to treat patients with advanced non-small cell lung cancer

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The U.S. Food and Drug Administration today approved Opdivo (nivolumab) to treat patients with advanced (metastatic) non-small cell lung cancer whose disease progressed during or after platinum-based chemotherapy.

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. The most common type of lung cancer, non-small cell lung cancer (NSCLC), is further divided into two main types named for the kinds of cells found in the cancer – squamous cell and non-squamous cell (which includes adenocarcinoma).Opdivo 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, Opdivo may help the body's immune system fight the cancer cells. Earlier this year, the FDA approved Opdivo to treat patients with advanced *squamous* NSCLC whose disease progressed during or after platinum-based chemotherapy. Today's approval expands the use of Opdivo to also treat patients with *non-squamous* NSCLC.

"There is still a lot to learn about the PD-1/PD-L1 pathway and its effects in lung cancer, as well as other tumor types," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "While Opdivo showed an overall survival benefit in certain non-small cell lung cancer patients, it appears that higher expression of PD-L1 in a patient's tumor predicts those most likely to benefit."

The safety and effectiveness of Opdivo for this use was demonstrated in an international, open-label, randomized study of 582 participants with advanced NSCLC whose disease progressed during or after treatment with platinum-based chemotherapy and appropriate biologic therapy. Participants were treated with Opdivo or docetaxel. The primary endpoint was overall survival, and the secondary endpoint was objective response rate (the percentage of patients who experienced complete or partial shrinkage of their tumors). Those treated with Opdivo lived an average of 12.2 months compared to 9.4 months in those treated with docetaxel. Additionally, 19 percent of those treated with Opdivo experienced a complete or partial shrinkage of their tumors, an effect that lasted an average of 17 months, compared to 12 percent among those taking docetaxel, which lasted an average of six months.

While patients who received Opdivo lived longer than those who received docetaxel across the study, an evaluation of samples from a subgroup of patients' tumors suggests that the level of PD-L1 expression in NSCLC tumors may help identify patients who are more likely to live longer due to treatment with Opdivo. Therefore, today the FDA also approved the PD-L1 IHC 28-8 pharmDx test to detect PD-L1 protein expression levels and help physicians determine which patients may benefit most from treatment with Opdivo.

The most common side effects of Opdivo are fatigue, musculoskeletal pain, decreased appetite, cough and constipation. Opdivo also has the potential to cause serious side effects that result from the immune system effect of Opdivo (known as "immune-mediated side effects"). These severe immune-mediated side effects involve healthy organs, including the lung, colon, liver, kidneys, hormone-producing glands and the brain.

The FDA granted Opdivo breakthrough therapy designation for this indication based on preliminary clinical evidence that suggested Opdivo may offer a substantial improvement over available therapies. It 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. The approval of Opdivo occurred approximately three months ahead of the prescription drug user fee goal date of January 2, 2016, the date when the agency was scheduled to complete its review of the application.

Another drug called Keytruda (pembrolizumab), manufactured by Merck, also targets the PD-1/PD-L1 pathway and was granted accelerated approval last week for treating NSCLC specifically for patients whose tumors expressed PD-L1.

Opdivo is marketed by Bristol-Myers Squibb based in Princeton, New Jersey. The PD-L1 IHC 28-8 pharmDx test is marketed by Dako North America Inc. in Carpinteria, California.

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