FDA approves expanded use of Opdivo in advanced lung cancer

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(HealthDay)—The U.S. Food and Drug Administration has approved Opdivo (nivolumab) to treat patients with advanced non-small-cell lung cancer (NSCLC) whose disease progressed despite platinum-based chemotherapy.

Opdivo works by targeting the PD-1/PD-L1 cellular pathway. The FDA approved Opdivo earlier this year to treat patients with advanced squamous NSCLC whose disease progressed despite platinum-based chemotherapy. This most recent approval expands the use of Opdivo for treatment of patients with non-squamous NSCLC.

The safety and effectiveness of Opdivo for non-squamous NSCLC were assessed in a study of 582 patients with advanced NSCLC who were treated with Opdivo or docetaxel. Participants treated with Opdivo lived

an average of 12.2 months, while those treated with docetaxel lived an average of 9.4 months. Nineteen percent of those treated with Opdivo experienced a complete or partial regression of their tumors, which lasted an average of 17 months, compared to 12 percent among those taking docetaxel, which lasted an average of six months. The most common side effects of Opdivo are fatigue, musculoskeletal pain, decreased appetite, cough, and constipation; there is also risk of immune-mediated side effects.

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 agency said in a news release.

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

More information: More Information