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# First-line immunotherapy treatment can improve survival for subset of lung cancer patients

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Findings from a phase III clinical trial for advanced lung cancer patients could help oncologists better predict which patients are likely to receive the most benefit from immunotherapy as a first-line treatment based on the unique molecular characteristics of their tumor, according to a new study reported by a global team led by David Carbone, MD, PhD, of The Ohio State University Comprehensive Cancer - Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC - James).

In this study, researchers compared the effectiveness of the immunotherapy drug nivolumab (pronounced "nye VOL ue mab," marketed at Opdivo), with standard-of-care chemotherapy in 541 patients with previously untreated or recurrent non-small cell lung cancer (NSCLC) that expressed PDL-1 antibodies.

Nivolumab is part of a class of immunotherapy drugs known as PD-1 blocking antibodies. These drugs work by targeting the PDL-1 receptor—a known immunotherapy biomarker for lung and other cancers—to boost immune responses to the cancer.

Patients were randomized to receive either immunotherapy or standard-of-care chemotherapy. About 60 percent of patients treated on the trial ultimately crossed over to the immunotherapy treatment arm due to disease progression.

Results from this new study showed that nivolumab did not result in longer progression-free survival compared with chemotherapy in the overall population. The response rate for patients receiving nivolumab was 26.1 percent, with a 12.1 month median duration of response before disease progression. The response rate for patients treated on the chemotherapy arm was 33.5 percent, but median duration of response was just 5.7 months before disease progression.

"The good news is that we discovered that a subset of patients who had both high tumor mutation burden and high PDL-1 positive status did experience a significant benefit from immunotherapy," says Carbone.

Patients with both high tumor mutation burden and high PDL-1 positive status had a 75 percent response rate compared with a 16 percent response rate to immunotherapy among patients with low mutation burden and low PDL-1. These same two groups had 25 percent and 23 percent response rates, respectively, when treated with chemotherapy, showing that these markers were selective for immunotherapy.

Understanding a patient's overall tumor burden through genomic testing, says Carbone, could help identify patients most likely to benefit from immunotherapy before therapy ever begins.

"This study is an important step toward understanding the impact of tumor mutation burden and PDL-1 in immunotherapy response. This data shows we should evaluate these two factors independently to most accurately define who will benefit from immunotherapy," says Carbone.

The findings are reported in the June 22, 2017, issue of the *New England Journal of Medicine*.

Provided by Ohio State University Medical Center

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