OPDIVO MORE THAN TRIPLED 5-YEAR SURVIVAL RATES IN NSCLC PATIENTS IN PHASE 1 STUDY

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Recent data from a Phase 1 study revealed that Opdivo-treated advanced non-small cell lung cancer (NSCLC) patients have durable responses and a five-year survival rate of 16%, which more than triples the 4.9% five-year survival rate seen in historical controls receiving standard-of-care.

The findings were recently presented at the American Association for Cancer Research (AACR) 2017 Annual Meeting in Washington, D.C. The study was titled "Five-year follow-up from the CA209-003 study of nivolumab in previously treated advanced non-small cell lung cancer (NSCLC): Clinical characteristics of long-term survivors."

"This is the first report of the long-term survival rate in patients with metastatic NSCLC treated with an immune checkpoint inhibitor. Our study results show that for a small subset of patients, immunotherapy can work for a very long time," Julie Brahmer, MD, associate professor of oncology at the Bloomberg-Kimmel Institute for Cancer Immunotherapy at Johns Hopkins, said in a press release.

"The five-year overall survival rate reported in this study is much higher than what is reported for this population of patients receiving standard-of-care treatment," Brahmer added. "Statistics show that most patients with advanced disease die within a year of diagnosis, and the five-year survival rate for metastatic NSCLC is about 4 percent."

The team used data from a cohort of the CA209-003 Phase 1 trial (NCT00730639), in which heavily pretreated, advanced NSCLC patients were assigned to three different

doses of Opdivo (1, 3, or 10 mg/kg), administered every two weeks in eight-week cycles, for up to 96 weeks. Patients were enrolled regardless of their tumor PD-L1 status.

Prior analysis of this trial revealed that Opdivo had encouraging activity in heavily treated NSCLC patients, and findings from subsequent Phase 3 trials led to the FDA's approval of Opdivo for this patient population.

Reports of long-term effectiveness and safety with immune checkpoint inhibitors are limited, which led the researchers to update the results from the trial after five years of follow-up, representing the longest survival follow-up for an immune checkpoint inhibitor in advanced NSCLC to date.

Among the 129 NSCLC patients included in the Phase 1 trial, the median five-year survival rate was 16%. Patients with squamous and non-squamous NSCLC had similar five-year survival rates: 16% and 15%, respectively.

Of the 16 patients who survived for five years or longer, nine were male and 12 were smokers at the time of enrollment. Nine patients completed the maximum number of Opdivo cycles.

Twelve of the 16 patients achieved a partial response, and two patients had stable disease as best overall response to Opdivo. According to Brahmer, none of the 12 patients who responded required further treatment.

"While this speaks to the durability of the responses, further evaluations would be needed to ascertain if the cancers were completely eliminated by the immune system, because of which no further treatment was needed, or if the therapy invoked an ongoing immune memory," Brahmer noted.

Among 10 responders evaluable for analysis, seven had PD-L1 expression of 1% or more, and three had PD-L1 expression lower than 1%. The presence of this ligand is usually used as a biomarker to predict which patients will respond to Opdivo, but in this study, PD-L1 status was not clearly associated with long-term survival in this patient population.

"We are performing further studies to learn why these patients did so well for so long and better understand which patients can stop treatment at two years and which of them need to continue treatment beyond two years," Brahmer said.