FDA Grants Opdivo Accelerated Approval for Third-Line Treatment of Metastatic Small-Cell Lung Cancer

Responses were durable for at least six months in 77% of responders.

August 21, 2018 By Food and Drug Administration (FDA)

FDA grants nivolumab accelerated approval for third-line treatment of metastatic small-cell lung cancer

On August 16, 2018, the Food and Drug Administration granted accelerated approval to nivolumab (Opdivo, Bristol-Myers Squibb Company Inc.) for patients with metastatic small-cell lung cancer (SCLC) with progression after platinum-based chemotherapy and at least one other line of therapy.

Approval was based on demonstration of a durable overall response rate (ORR) in a subgroup of patients from CheckMate-032 (NCT01928394), a multicenter, open-label trial in patients with metastatic solid tumors. This subgroup comprised 109 patients with metastatic SCLC, with disease progression after platinum-based therapy and at least one other prior line of therapy, regardless of tumor PD-L1 status. All patients received nivolumab 3 mg/kg by intravenous infusion over 60 minutes every 2 weeks.

The major efficacy outcome measures were overall response rate (ORR) and duration of response according to RECIST v1.1 as assessed by blinded independent central review. The ORR was 12% (95% CI: 6.5, 19.5). Responses were durable for 6 months or longer in 77%, 12 months or longer in 62%, and 18 months or longer in 39% of the 13 responding patients. PD-L1 tumor status did not appear to be predictive of response.

Safety data was evaluated in 245 patients with metastatic SCLC with disease progression following platinum-based chemotherapy and received at least one dose of nivolumab at a dose of 3 mg/kg every 2 weeks. The most common (≥20%) adverse reactions in CheckMate-032 were fatigue, decreased appetite, musculoskeletal pain, dyspnea, nausea, diarrhea, constipation and cough. Nivolumab was discontinued for adverse reactions in 10% of patients and 25% of patients had at least one dose withheld for an adverse reaction. Serious adverse reactions occurred in 45% of patients. The most frequent (≥2%) serious adverse reactions were pneumonia, dyspnea, pneumonitis, pleural effusion, and dehydration.

The recommended dose and schedule of nivolumab for this indication is 240 mg every 2 weeks over 30 min.

View full prescribing information for Opdivo.

This application was granted Priority Review. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

This announcement was originally published on the Food and Drug Administration website on August 16, 2018.
