Generic Name:
Nivolumab
Trade Name:
Opdivo
Company:
Bristol-Myers Squibb
Notes:

FDA granted accelerated approval to nivolumab 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, 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 I.V. infusion over 60 minutes every 2 weeks.

The ORR was 12%. 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 were 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 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.

Medication Monitor Categories:
Supplemental Approvals