Generic Name:
Pembrolizumab
Trade Name:
Keytruda
Company:
Merck
Notes:

FDA approved a new indication for pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel as first-line treatment of metastatic squamous non?small cell lung cancer (NSCLC).

Approval was based on a randomized, multicenter, double-blind, placebo-controlled trial in 559 patients with metastatic squamous NSCLC, regardless of PD-L1 tumor expression status, who had not previously received systemic therapy for metastatic disease.

Patients were randomized (1:1) to pembrolizumab 200 mg or placebo in combination with carboplatin, along with either paclitaxel every 3 weeks or nab-paclitaxel weekly on a 3-week cycle for four cycles, followed by pembrolizumab or placebo. Patients continued pembrolizumab or placebo until disease progression, unacceptable toxicity, or a maximum of 24 months.

The trial demonstrated statistically significant improvements in patients receiving pembrolizumab plus chemotherapy compared with those randomized to placebo plus chemotherapy.

The most common adverse reactions in at least 20% of patients who received pembrolizumab were fatigue/asthenia, nausea, constipation, diarrhea, vomiting, pyrexia, decreased appetite, rash, cough, dyspnea, alopecia, and peripheral neuropathy.

The recommended pembrolizumab dose for metastatic squamous NSCLC is 200 mg intravenously every 3 weeks, prior to chemotherapy when given on the same day, until disease progression, unacceptable toxicity, or 24 months after initiation.

Medication Monitor Categories:
Supplemental Approvals