

Supplemental Approvals

Generic Name (Trade Name—Company)

November 1, 2018

Pembrolizumab

(Keytruda—Merck)

In combination with chemotherapy, drug approved for first-line treatment of metastatic squamous NSCLC

Uses/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.

Source URL:

<http://aphanet.org/supplemental-approvals/combination-chemotherapy-drug-approved-first-line-treatment-metastatic>

A^{PhA} DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in A^{PhA} DrugInfoLine do not necessarily

represent the policy, recommendations, or endorsement of APhA. The publisher, authors, editors, reviewers, and contributors have taken care to ensure that information contained in APhA DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.