FDA Approves Opdivo Plus Yervoy for Lung Cancer With PD-L1 Expression

The combination led to improved overall survival compared with chemotherapy.

May 21, 2020 By Food and Drug Administration (FDA)

FDA approves nivolumab plus ipilimumab for first-line mNSCLC (PD-L1 tumor expression ≥1%)

On May 15, 2020, the Food and Drug Administration approved the combination of nivolumab (OPDIVO, Bristol-Myers Squibb Co.) plus ipilimumab (YERVOY, Bristol-Myers Squibb Co.) as first-line treatment for patients with metastatic non-small cell lung cancer whose tumors express PD-L1(≥1%), as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Today, the FDA also approved the PD-L1 IHC 28-8 pharmDx (Agilent Technologies, Inc.) as a companion diagnostic device for selecting patients with NSCLC for treatment with nivolumab plus ipilimumab.

Efficacy was investigated in CHECKMATE-227 (NCT02477826), a randomized, open-label, multi-part trial in patients with metastatic or recurrent NSCLC and no prior anticancer therapy. In Part 1a of the trial, 793 patients with PD-L1 tumor expression ≥1% were randomized to receive either the combination of nivolumab plus with ipilimumab (n=396) or platinum-doublet chemotherapy (n=397).

The trial demonstrated a statistically significant improvement in overall survival (OS) for patients with PD-L1 tumor expression ≥1% receiving nivolumab plus ipilimumab compared to those treated with platinum-doublet chemotherapy. Median OS was 17.1 months (95% CI: 15, 20.1) versus 14.9 (95% CI: 12.7, 16.7) (HR 0.79; 95% CI: 0.67, 0.94; p=0.0066).

Median progression-free survival (PFS) per blinded independent central review (BICR) was 5.1 months (95% CI: 4.1, 6.3) in the nivolumab plus ipilimumab arm and 5.6 months (95% CI: 4.6, 5.8) in the platinum-doublet chemotherapy arm (HR 0.82; 95% CI: 0.69, 0.97). Confirmed overall response rate (ORR) per BICR was 36% (95% CI: 31, 41) and 30% (95% CI: 26, 35), respectively. Median response duration was 23.2 months in the nivolumab plus ipilimumab arm and 6.2 months in the platinum-doublet chemotherapy arm.

The most common adverse reactions in ≥20% of patients receiving the combination of nivolumab

plus ipilimumab in CHECKMATE-227 were fatigue, rash, decreased appetite, musculoskeletal pain, diarrhea/colitis, dyspnea, cough, pruritis, nausea, and hepatitis.

The recommended doses for metastatic NSCLC are nivolumab 3 mg/kg every 2 weeks and ipilimumab 1 mg/kg every 6 weeks until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression.

View full prescribing information for OPDIVO.
View full prescribing information for YERVOY.

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 May 15, 2020.
