FDA Approves Opdivo Plus Yervoy With Chemotherapy for Metastatic Lung Cancer

Adding the immunotherapy combination improved survival compared with chemotherapy alone.

May 29, 2020 By Food and Drug Administration (FDA)

FDA approves nivolumab plus ipilimumab and chemotherapy for first-line treatment of metastatic NSCLC

On May 26, 2020, the Food and Drug Administration approved the combination of nivolumab (OPDIVO, Bristol-Myers Squibb Co.) plus ipilimumab (YERVOY, Bristol-Myers Squibb Co.) and 2 cycles of platinum-doublet chemotherapy as first-line treatment for patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Efficacy was investigated in CHECKMATE-9LA (NCT03215706), a randomized, open-label trial in patients with metastatic or recurrent NSCLC. Patients were randomized to receive either the combination of nivolumab plus ipilimumab and 2 cycles of platinum-doublet chemotherapy (n=361) or platinum-doublet chemotherapy for 4 cycles (n=358).

The trial demonstrated a statistically significant benefit in overall survival (OS) for patients treated with nivolumab plus ipilimumab plus chemotherapy compared to those who received chemotherapy. Median OS was 14.1 months (95% CI: 13.2, 16.2) versus 10.7 months (95% CI: 9.5, 12.5), HR 0.69; 96.71% CI: 0.55, 0.87).

Median progression-free survival (PFS) per blinded independent central review (BICR) was 6.8 months (95% CI: 5.6, 7.7) in the nivolumab plus ipilimumab and chemotherapy arm and 5 months (95% CI: 4.3, 5.6) in the chemotherapy arm (HR 0.70; 95% CI: 0.57, 0.86). Confirmed overall response rate (ORR) per BICR was 38% (95% CI: 33, 43) and 25% (95% CI: 21, 30) respectively.

Median response duration was 10 months in the nivolumab plus ipilimumab and chemotherapy arm, and 5.1 months in the chemotherapy arm.

The most common adverse reactions in ≥20% of patients receiving nivolumab in combination with ipilimumab and platinum-doublet chemotherapy were fatigue, musculoskeletal pain, nausea,

diarrhea, rash, decreased appetite, constipation, and pruritus.

The recommended nivolumab dose for this indication is 360 mg every 3 weeks with ipilimumab 1 mg/kg every 6 weeks and 2 cycles of platinum-doublet chemotherapy. The nivolumab and ipilimumab is continued 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.

FDA collaborated with the Australian Therapeutic Goods Administration (TGA), Health Canada, and Singapore's Health Sciences Authority (HSA) on the review of this application as part of Project Orbis. FDA approved this application 2 months ahead of schedule. The FDA and HSA decisions are near-simultaneous, while the review of the applications is ongoing for the Australian TGA and Health Canada.

This review used the Real-Time Oncology Review (RTOR), which streamlined data submission prior to the filing of the entire clinical application, and the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review and fast track designation. 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 26, 2020.
