FDA Approves Opdivo Plus Yervoy for Mesothelioma

The immunotherapy combo improved overall survival compared with chemotherapy.

October 5, 2020 By Food and Drug Administration (FDA)

FDA approves nivolumab and ipilimumab for unresectable malignant pleural mesothelioma

On October 2, 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 adult patients with unresectable malignant pleural mesothelioma.

Efficacy was investigated in CHECKMATE-743 (NCT02899299), a randomized, open-label trial in patients with unresectable malignant pleural mesothelioma and no prior anticancer therapy. Patients were randomized to receive either nivolumab and ipilimumab for up to 2 years (n=303) or 6 cycles of combination chemotherapy with cisplatin or carboplatin plus pemetrexed (n=302).

The trial demonstrated a statistically significant improvement in overall survival (OS) for patients treated with nivolumab plus ipilimumab compared with those who received chemotherapy. Median OS was 18.1 months (95% CI: 16.8, 21.5) versus 14.1 months (95% CI: 12.5, 16.2) (HR 0.74; 95% CI: 0.61, 0.89; p=0.002).

Median progression-free survival per blinded independent central review (BICR) was 6.8 months (95% CI: 5.6, 7.4) in the nivolumab plus ipilimumab arm and 7.2 months (95% CI: 6.9, 8.1) in the chemotherapy arm (HR 1.0; 95% CI 0.82, 1.21). Confirmed overall response rate per BICR was 40% (95% CI: 34, 45) and 43% (95% CI 37, 49) in the nivolumab plus ipilimumab and chemotherapy arms, respectively. Median response duration was 11.0 months in the nivolumab plus ipilimumab arm and 6.7 months in the chemotherapy arm.

The most common adverse reactions (incidence ≥ 20%) in patients receiving the combination of nivolumab plus ipilimumab in CHECKMATE-743 were fatigue, musculoskeletal pain, rash, diarrhea, dyspnea, nausea, decreased appetite, cough, and pruritus.

The recommended doses for unresectable malignant pleural mesothelioma are nivolumab 360 mg every 3 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 review was conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among international partners. For this review, FDA collaborated with the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Regulatory Agency (ANVISA), Health Canada, and Switzerland's Swissmedic. The application reviews are ongoing at the other regulatory agencies. FDA approval occurred approximately 5 months ahead of the goal date.

This review used the Real-Time Oncology Review (RTOR) pilot program and the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment. The applications were granted priority review and orphan product 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.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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