Opdivo® (nivolumab), Yervoy® (ipilimumab) – New indication

- On May 15, 2020, Bristol Myers Squibb announced the FDA approval of Opdivo (nivolumab), as first-line treatment in combination with Yervoy (ipilimumab) in adult patients with metastatic non-small cell lung cancer (NSCLC) expressing PD-L1 (≥ 1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

    — Yervoy's drug label reflects the same new indication.

- Opdivo is also approved for the treatment of unresectable and metastatic melanoma; melanoma with lymph node involvement; metastatic NSCLC and progression on or after platinum-based chemotherapy; metastatic small cell lung cancer; advanced renal cell carcinoma; intermediate or poor risk, previously untreated advanced renal cell carcinoma; adult patients with classical Hodgkin lymphoma that has relapsed or progressed; recurrent or metastatic squamous cell carcinoma of the head and neck; locally advanced or metastatic urothelial carcinoma; adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer; and hepatocellular carcinoma.

- Yervoy is also approved for the treatment of unresectable or metastatic melanoma; cutaneous melanoma with pathologic involvement of regional lymph nodes; intermediate or poor-risk, previously untreated advanced renal cell carcinoma; adult and pediatric patients 12 years of age and older with MSI-H or mismatch repair deficient metastatic colorectal cancer; and hepatocellular carcinoma.

- The FDA approval for the new indication was based on Part 1a of the CHECKMATE-227 open-label study. A total of 793 patients with metastatic or recurrent NSCLC with PD-L1 ≥ 1% were randomized to receive Opdivo + Yervoy or platinum-doublet chemotherapy. The primary efficacy outcome measure was overall survival (OS). Additional efficacy outcome measures included progression free survival (PFS), objective response rate (ORR), and duration of response (DOR).

    — The median OS for patients treated with Opdivo + Yervoy was 17.1 months vs. 14.9 months for the platinum-doublet chemotherapy patients (Hazard Ratio (HR): 0.79; 95% CI: 0.67, 0.94; p = 0.0066).
    — The median PFS was 5.1 months for the Opdivo + Yervoy arm vs. 5.6 months for the platinum-doublet chemotherapy arm (HR: 0.82; 95% CI: 0.69, 0.97).
    — The ORR and DOR for the Opdivo + Yervoy arm was 36% (95% CI: 31, 41) and 23.2 months vs. 30% (95% CI: 26, 35) and 6.2 months for the platinum-doublet chemotherapy arm, respectively.

- Yervoy carries a boxed warning for immune-mediated adverse reactions.

- The most common adverse events (≥ 20%) with Opdivo + Yervoy use were fatigue, diarrhea, rash, pruritus, nausea, musculoskeletal pain, pyrexia, cough, decreased appetite, vomiting, abdominal pain, dyspnea, upper respiratory tract infection, arthralgia, headache, hypothyroidism, decreased weight, and dizziness.

- The recommended dose for Opdivo for the treatment of metastatic NSCLC expressing PD-L1 is 3 mg/kg intravenously (IV) every 2 weeks with Yervoy 1 mg/kg IV every 6 weeks. Use Opdivo in combination with Yervoy until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression.

Continued . . .

- Information on FDA-approved tests for the determination of PD-L1 expression in NSCLC is available at http://www.fda.gov/CompanionDiagnostics.
- Refer to the Yervoy drug label for further dosing recommendations and for dosing for other indications.
- Refer to the Opdivo drug label for dosing recommendations for all other indications.

optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

RxNews® is published by the OptumRx Clinical Services Department.