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

- On May 26, 2020, Bristol Myers Squibb announced the FDA approval of Opdivo (nivolumab), in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy, for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC), 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 melanoma; other scenarios of NSCLC; small cell lung cancer; renal cell carcinoma; classical Hodgkin lymphoma; squamous cell carcinoma of the head and neck; urothelial carcinoma; microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer; and hepatocellular carcinoma.
- Yervoy is also approved for the treatment of melanoma; other scenarios of NSCLC; renal cell carcinoma; MSI-H or dMMR metastatic colorectal cancer; and hepatocellular carcinoma.
- The FDA approval for the new indication was based on CHECKMATE-9LA, an open-label trial in 719 patients with metastatic or recurrent NSCLC. Patients were randomized to receive Opdivo + Yervoy + platinum-doublet chemotherapy 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).
    - During the interim analysis, the median OS for patients treated with Opdivo + Yervoy + platinum-doublet chemotherapy was 14.1 months vs. 10.7 months for the platinum-doublet chemotherapy patients (Hazard Ratio [HR]: 0.69; 96.71% CI: 0.55, 0.87; p = 0.0006).
    - The median PFS was 6.8 months (95% CI: 5.6, 7.7) for the Opdivo + Yervoy + platinum chemotherapy arm vs. 5.0 months (95% CI: 4.3, 5.6) for the platinum-doublet chemotherapy arm.
    - The ORR and DOR for the Opdivo + Yervoy + platinum-doublet chemotherapy arm was 38% (95% CI: 33, 43) and 10.0 months (95% CI: 8.2, 13.0) vs. 25% (95% CI: 21, 30) and 5.1 months (95% CI: 4.3, 7.0) 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 + platinum-doublet chemotherapy use were fatigue, musculoskeletal pain, nausea, diarrhea, rash, decreased appetite, constipation, and pruritus.
- The recommended dose of Opdivo for the treatment of metastatic or recurrent NSCLC is 360 mg intravenously (IV) every 3 weeks with Yervoy 1 mg/kg IV every 6 weeks and histology-based platinum-doublet chemotherapy every 3 weeks for 2 cycles. Opdivo should be used in combination with Yervoy until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression.

Continued . . .

- 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.

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