Checkmate 9LA

Overall survival

- Includes pruritus and generalized pruritus.
- Includes vertigo and positional vertigo.

Common Adverse Reactions

Lactation

Other Immune-Mediated Adverse Reactions

Serious Adverse Reactions

In Checkmate 227, serious adverse reactions occurred in 58% of patients (n=576). The most frequent (≥2%) serious adverse reactions were pneumonia, diarrhea, febrile neutropenia, and transaminases increased.

Key Trials

- ORR was 38% (95% CI: 33–43) with OPDIVO + YERVOY with chemo and 25% (95% CI: 21–30) with chemo alone.
- Grade 3 (3.5%), and Grade 2 (4.0%) immune-mediated pneumonitis. Four patients (0.7%) died due to pneumonitis. The incidence and severity of immune-mediated pneumonitis. Administer corticosteroids for Grade 2 or more severe pneumonitis. Permanently discontinue for Grade 3 or 4 and withhold until resolution for Grade 2.

OPDIVO can cause immune-mediated pneumonitis. Fatal cases have been reported. Monitor patients for signs with radiographic imaging and for symptoms of pneumonitis and myasthenic syndrome.

OPDIVO can cause immune-mediated hepatitis. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or more severe hepatitis. Permanently discontinue for Grade 3 or 4 and withhold until resolution for Grade 2.

OPDIVO can cause immune-mediated encephalitis. Evaluation of patients with neurologic symptoms may include, but not be limited to, consultation with a neurologist. If confirmed, permanently discontinue.

Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consideration should be given to systemic immunosuppression. OPDIVO and YERVOY are not recommended in patients requiring systemic immunosuppression were excluded from the study. Tumor specimens were evaluated prospectively using the PD-L1 IHC 28-8 pharmDx assay at a central laboratory.

Study design:

- Efficacy results from a pre-specified interim analysis when 351 events were observed (87% of the planned number of events for final analysis) with an 8.1-month follow-up.
- In Checkmate 227 Part 1a, PFS, ORR, and DOR were pre-specified descriptive analyses. The primary efficacy outcome measure was OS.
- OS in patients with tumor PD-L1 expression ≥1% (primary analysis) was 17.0 months (95% CI: 14.7–19.3) with OPDIVO + YERVOY and 13.6 months (95% CI: 11.8–15.7) with chemo (HR=0.79; 95% CI: 0.67–0.94; p=0.003).
- ORR was 38% (95% CI: 33–43) with OPDIVO + YERVOY with chemo and 25% (95% CI: 21–30) with chemo alone.
- Median DOR in patients with tumor PD-L1 expression ≥1% (primary analysis) was 8.9 months (95% CI: 5.0–16.7) for OPDIVO + YERVOY compared to 2.5 months (95% CI: 2.1–3.7) for chemo (HR=0.51; 95% CI: 0.30–0.86).

In Checkmate 227, serious adverse reactions occurred in 57% of patients (n=358). The most frequent (>2%) serious adverse reactions were pneumonia, diarrhea, febrile neutropenia, and transaminases increased.

Summary of Warnings and Precautions

- BOXED WARNING regarding immune-mediated adverse reactions.
- OPDIVO can cause immune-mediated adverse reactions, including but not limited to colitis, hepatitis, endocrinopathies, exfoliative dermatitis, uveitis, and others, and can occur at any time during treatment. In cases of corticosteroid-refractory colitis, consideration should be given to systemic immunosuppression. Tumor specimens were evaluated prospectively using the PD-L1 IHC 28-8 pharmDx assay at a central laboratory.
- OPDIVO can cause immune-mediated pneumonitis. Fatal cases have been reported. Monitor patients for signs with radiographic imaging and for symptoms of pneumonitis and myasthenic syndrome.
- OPDIVO can cause immune-mediated hepatitis. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or more severe hepatitis. Permanently discontinue for Grade 3 or 4 and withhold until resolution for Grade 2.
- OPDIVO can cause immune-mediated encephalitis. Evaluation of patients with neurologic symptoms may include, but not be limited to, consultation with a neurologist. If confirmed, permanently discontinue.
- OPDIVO can cause immune-mediated colitis requiring systemic immunosuppression were excluded from the study. Tumor specimens were evaluated prospectively using the PD-L1 IHC 28-8 pharmDx assay at a central laboratory.
- Some serious adverse reactions were reported at a higher frequency with OPDIVO + YERVOY compared to chemo alone.
- Treatment was permanently discontinued for adverse reactions in 24% of patients treated with OPDIVO + YERVOY with chemo, and 56% had at least one dose reduction in treatment-related adverse reactions.

Now Approved

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