

Supplemental Approvals

Generic Name (Trade Name) Company

April 16, 2018

Nivolumab and ipilimumab

Uses/Notes

[FDA granted approvals](#) to nivolumab and ipilimumab in combination to treat intermediate or poor risk, previously untreated advanced renal cell carcinoma.

Approvals were based on CheckMate 214 (NCT02231749), a randomized open-label trial. Patients with previously untreated advanced RCC received nivolumab (3 mg/kg) plus ipilimumab (1 mg/kg) every 3 weeks for four doses, followed by nivolumab monotherapy (3 mg/kg) every 2 weeks, or sunitinib 50 mg daily for 4 weeks followed by 2 weeks off every cycle.

Efficacy was evaluated in intermediate or poor-risk patients (n = 847). The trial demonstrated statistically significant improvements in overall survival (OS) and objective response rate (ORR) for patients receiving the combination (n = 425) compared with those receiving sunitinib (n = 422). Estimated median OS was not estimable in the combination arm compared with 25.9 months in the sunitinib arm (hazard ratio 0.63 [95% CI 0.44–0.89]; P P

The most common adverse reactions (reported in at least 20% of patients treated with the combination) were fatigue, rash, diarrhea, musculoskeletal pain, pruritus, nausea, cough, pyrexia, arthralgia, and decreased appetite.

The recommended schedule and dose for this combination is nivolumab 3 mg/kg, followed by ipilimumab 1 mg/kg on the same day every 3 weeks for four doses, then nivolumab 240 mg every 2 weeks or 480 mg every 4 weeks.

Prescribing information for both nivolumab and ipilimumab have been updated with these results. Full prescribing information is available at:

nivolumab

PI:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125554s058lbl.pdf

(Opdivo and Yervoy—Bristol-Myers Squibb) ipilimumab

PI:

FDA approves nivolumab plus ipilimumab combination for intermediate or poor-risk advanced renal cell carcinoma

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125377s094lbl.pdf

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