Supplemental Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
April 16, 2018	
Nivolumab and ipilimumab	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)

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

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

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