

FDA Approves Opdivo plus Yervoy Combination for Advanced Kidney Cancer

Dual checkpoint inhibitors improve response rate and survival for people with intermediate or poor risk.

April 16, 2018 By [Food and Drug Administration \(FDA\)](#)

On April 16, 2018, the Food and Drug Administration granted approvals to nivolumab and ipilimumab (Opdivo and Yervoy, Bristol-Myers Squibb Co.) in combination for the treatment of intermediate or poor risk, previously untreated advanced renal cell carcinoma.

The 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 4 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; $p < 0.0001$). The ORR was 41.6% (95% CI: 36.9, 46.5) for the combination versus 26.5% (95% CI: 22.4, 31) in the sunitinib arm ($p < 0.0001$). The efficacy of the combination in patients with previously untreated renal cell carcinoma with favorable-risk disease was not established.

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 4 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

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

FDA granted these applications priority review and breakthrough therapy designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at <http://www.fda.gov/medwatch/report.htm>, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

This announcement [originally appeared](#) on the Food and Drug Administration website on April 16, 2018.

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<http://beta.docker.cancerhealth.com/blog/fda-approves-opdivo-plus-yervoy-combination-advanced-kidney-cancer>