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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