FDA Approves Opdivo Plus Cabometyx for Advanced Kidney Cancer

The immunotherapy combination slowed disease progression and reduced the risk of death by 40%.

February 3, 2021 By Food and Drug Administration (FDA)

FDA approves nivolumab plus cabozantinib for advanced renal cell carcinoma

On January 22, 2021, the Food and Drug Administration approved the combination of nivolumab (Opdivo, Bristol-Myers Squibb Co.) and cabozantinib (Cabometyx, Exelixis) as first-line treatment for patients with advanced renal cell carcinoma (RCC).

Efficacy was evaluated in CHECKMATE-9ER (NCT03141177), a randomized, open-label trial in patients with previously untreated advanced RCC. Patients were randomized to receive either nivolumab 240 mg over 30 minutes every 2 weeks in combination with cabozantinib 40 mg orally once daily (n=323) or sunitinib 50 mg orally daily for the first 4 weeks of a 6-week cycle (4 weeks on treatment followed by 2 weeks off) (n=328).

The trial demonstrated a statistically significant improvement in progression-free survival (PFS), overall survival (OS) and confirmed overall response rate (ORR) for patients treated with nivolumab plus cabozantinib compared with those who received sunitinib. Median PFS per blinded independent central review (BICR) was 16.6 months versus 8.3 months; HR 0.51 (95% CI: 0.41, 0.64). Median OS was not reached in either arm; HR 0.60 (95% CI: 0.40, 0.89). Confirmed ORR per BICR was 55.7% and 27.1% in the nivolumab plus cabozantinib and sunitinib arms, respectively.

The most common adverse reactions (≥ 20%) in patients receiving the combination of nivolumab and cabozantinib were diarrhea, fatigue, hepatotoxicity, palmar-plantar erythrodysaesthesia syndrome, stomatitis, rash, hypertension, hypothyroidism, musculoskeletal pain, decreased appetite, nausea, dysgeusia, abdominal pain, cough, and upper respiratory tract infection.

The recommended dose is nivolumab 240 mg every 2 weeks (30-minute intravenous infusion) or 480 mg every 4 weeks (30-minute intravenous infusion) in combination with cabozantinib 40 mg orally once daily without food until disease progression or unacceptable toxicity.

View full prescribing information for Opdivo.
View full prescribing information for Cabometyx.

The nivolumab review used the Real-Time Oncology Review (RTOR) pilot program, which streamlined data submission prior to the filing of the entire clinical application. Both the nivolumab and the cabozantinib applications used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment. The FDA approved this application approximately one month ahead of the FDA goal date.

The nivolumab application was granted fast track review, and both the nivolumab and cabozantinib applications were granted priority review. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

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 or by calling 1-800-FDA-1088.

This announcement was originally published on the Food and Drug Administration website on January 22, 2021.
