FDA Approves Bavencio for Bladder Carcinoma Maintenance Treatment

The immunotherapy is now approved for people whose cancer has not progressed on platinum-based chemotherapy.

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FDA approves avelumab for urothelial carcinoma maintenance treatment

On June 30, 2020, the Food and Drug Administration approved avelumab (BAVENCIO, EMD Serono, Inc.) for maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy.

Efficacy of avelumab for maintenance treatment of UC was investigated in the JAVELIN Bladder 100 trial (NCT02603432), a randomized, multi-center, open-label trial that enrolled 700 patients with unresectable, locally advanced or metastatic urothelial carcinoma that had not progressed with four to six cycles of first-line platinum-containing chemotherapy. Patients were randomized (1:1) to receive either avelumab intravenously every 2 weeks plus best supportive care (BSC) or BSC alone. Treatment was initiated within 4-10 weeks after last chemotherapy dose.

The main efficacy outcome measures were overall survival (OS) in all patients and in patients with PD-L1-positive tumors. The median OS in all patients was 21.4 months in the avelumab arm and 14.3 months in the BSC alone arm (HR: 0.69; 95%CI: 0.56, 0.86; p=0.001). Among patients with PD-L1-positive tumors (51%), the HR for OS was 0.56 (95% CI: 0.40, 0.79; p<0.001). In an exploratory analysis of patients with PD- L1- negative tumors (39%), the OS hazard ratio was 0.85 (95% CI: 0.62, 1.18).

The most common adverse reactions in > 20% of patients who received avelumab were fatigue, musculoskeletal pain, urinary tract infection, and rash. One patient died from sepsis and 28% of patients had serious adverse reactions.

The recommended avelumab dose is 800 mg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

The results from this study supported the conversion of accelerated approval of avelumab to a regular approval.

View full prescribing information for BAVENCIO.

This review used Real-Time Oncology Review (RTOR), which streamlined data submission prior to the filing of the entire clinical application, and also used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment. This application was approved 3 months prior to the FDA goal date.

Avelumab was granted priority review and breakthrough therapy designation in this setting. 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 June 30, 2020.
