Avelumab and axitinib approved for treatment of renal cell carcinoma

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(HealthDay)—Avelumab (BAVENCIO) was approved this week for

first-line treatment of advanced renal cell carcinoma (RCC) in combination with axitinib, the U.S. Food and Drug Administration announced.

The agency based the approval on data from the JAVELIN Renal 101 trial, a randomized, multicenter, open-label trial of avelumab combined with axitinib. The trial included 886 patients with previously untreated advanced RCC who were randomly assigned either to treatment with 10 mg/kg avelumab intravenous infusion every two weeks plus 5 mg oral axitinib twice daily or to treatment with 50 mg oral sunitinib once daily for four weeks followed by two weeks off.

The researchers found that median progression-free survival was 13.8 months for patients who received avelumab plus axitinib and 8.4 months for patients who received sunitinib. The FDA notes that the overall survival data were immature, and at 19 months, the death rate was 27 percent in the intent-to-treat population. Nine percent of patients experienced grade 3 to 4 toxicity, which led to permanent discontinuation in 7 percent. Seven percent of patients in the trial had major cardiac adverse events.

Recommended dosing of avelumab is an intravenous infusion of 800 mg every two weeks combined with 5 mg oral axitinib twice daily. Commonly reported adverse reactions with avelumab plus axitinib include diarrhea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, dyspnea, abdominal pain, and headache. The manufacturer's labeling information directs clinicians to inform patients of the risk for pneumonitis, hepatitis, colitis, endocrinopathies, nephritis, and renal dysfunction.

Approval was granted to EMD Serono.

More information: More Information