FDA approves pembrolizumab plus axitinib for advanced RCC

April 23 2019

(HealthDay)—The combination of pembrolizumab and axitinib has been

approved as a first-line treatment in advanced renal cell carcinoma (RCC), the U.S. Food and Drug Administration announced Friday.

The agency approved the drug combination based on results from the KEYNOTE-426 trial, a randomized, multicenter, open-label trial of 861 patients. At enrollment, patients had not received systemic therapy for advanced RCC and were randomly assigned to either 200 mg of intravenous pembrolizumab every three weeks plus 5 mg of axitinib orally twice daily or to 50 mg of sunitinib once daily for four weeks and then off treatment for two weeks.

At 12 months, overall survival rates were 90 percent among patients treated with pembrolizumab plus axitinib and 78 percent among patients treated with sunitinib. Median progression-free survival was 15.1 and 11.1 months for those who received pembrolizumab plus axitinib and those who received sunitinib, respectively. Twenty percent of patients experienced grade 3 or 4 toxicity, and 13 percent of patients permanently discontinued pembrolizumab and axitinib because of hepatotoxicity. Commonly reported adverse reactions included diarrhea, fatigue/asthenia, hypertension, hypothyroidism, hepatotoxicity, palmar-plantar erythrodysesthesia, nausea, stomatitis/mucosal inflammation, dysphonia, rash, cough, decreased appetite, and constipation.

The recommended doses for this indication are 200 mg of pembrolizumab every three weeks and 5 mg of orally administered axitinib twice a day. According to the manufacturer's prescribing information, pembrolizumab should be administered as an intravenous infusion over 30 minutes. Patients should continue the drug combination until disease progression, unacceptable toxicity, or up to 24 months. The initial 5-mg dose of axitinib may be considered for dose escalation at six-week intervals.

More information: More Information