Pembrolizumab plus axitinib approved for RCC

June 2019—The Food and Drug Administration approved pembrolizumab (Keytruda, Merck) plus axitinib for the first-line treatment of patients with advanced renal cell carcinoma. Approval was based on Keynote-426, a randomized, multicenter, open-label trial conducted in 861 patients who had not received systemic therapy for advanced renal cell carcinoma. Patients were enrolled regardless of PD-L1 tumor expression status.

The main efficacy measures were overall survival and progression-free survival, assessed by blinded independent central review. The trial demonstrated a statistically significant improvement in OS in a pre-specified interim analysis for patients on the pembrolizumab plus axitinib arm (HR, 0.53; 95 percent CI, 0.38, 0.74; P<0.0001). With deaths reported in 18 percent of patients, the median OS was not reached in either arm. The 12-month OS rate was 90 percent in the pembrolizumab plus axitinib arm and 78 percent for those treated with sunitinib. The trial also demonstrated a PFS improvement for patients receiving pembrolizumab plus axitinib (HR, 0.69; 95 percent CI, 0.57, 0.84; P=0.0001). Median PFS was 15.1 and 11.1 months for those receiving pembrolizumab plus axitinib versus sunitinib, respectively.

Merck, 908-740-4000