Keytruda for HCC gets accelerated approval

February 2019—The FDA granted accelerated approval to pembrolizumab (Keytruda, Merck) for patients with hepatocellular carcinoma who have been previously treated with sorafenib.

Approval was based on KEYNOTE 224, a single-arm, multicenter trial enrolling 104 patients with hepatocellular carcinoma. Patients were required to have disease progression on or after sorafenib or were intolerant to sorafenib, have measurable disease, and Child-Pugh class A liver impairment. Twenty-one percent of the patients enrolled were HBV seropositive, 25 percent were HCV seropositive, and nine patients (nine percent) were seropositive for both HBV and HCV. Patients received pembrolizumab 200 mg as an intravenous infusion every three weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

Merck, 800-444-2080