FDA expands use of pembrolizumab for NCSLC

May 1, 2019—The Food and Drug Administration approved pembrolizumab (Keytruda, Merck) for the first-line treatment of patients with stage III non-small cell lung cancer who are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC. Patients' tumors must have no EGFR or ALK genomic aberrations and express PD-L1 (tumor proportion score ≥1 percent) determined by an FDA-approved test. Pembrolizumab was previously approved as a single agent for the first-line treatment of patients with metastatic NSCLC whose tumors express PD-L1 TPS ≥50 percent.

Approval was based on Keynote-042, a randomized, multicenter, open-label, active-controlled trial conducted in 1,274 patients with stage III or IV NSCLC who had not received prior systemic treatment for metastatic NSCLC and whose tumors expressed PD-L1 (TPS ≥1 percent). PD-L1 expression was determined by an immunohistochemistry assay using the PD-L1 IHC 22C3 pharmDx Kit (Agilent Technologies).