Agilent PD-L1 assay FDA approved as CDx

May 19, 2020—Agilent Technologies announced that the Food and Drug Administration has approved the company's PD-L1 IHC 28-8 pharmDx for expanded use in non-small cell lung cancer.

Physicians will be able to use the PD-L1 IHC 28-8 pharmDx assay as an aid in identifying patients with metastatic NSCLC for treatment with the dual immunotherapy combination of Opdivo (nivolumab) and Yervoy (ipilimumab). Based on the results of the phase three CheckMate -227 clinical trial, Opdivo in combination with Yervoy was approved as first-line treatment for patients with metastatic NSCLC whose tumors express PD-L1 (greater than or equal to one percent) as determined by an FDA-approved test.

Agilent developed the assay in 2016 through a collaboration with Bristol Myers Squibb; it was previously approved as a complementary in vitro diagnostic for non-squamous non-small cell lung cancer, as well as for squamous cell carcinoma of the head and neck, and urothelial carcinoma. Opdivo and Yervoy are manufactured by Bristol-Myers Squibb.