Quest expands oncology immunotherapy menu, 3/16

March 2016—Quest Diagnostics will offer clinical laboratory testing using Dako's PD-L1 IHC 28-8 pharmDx qualitative test, an FDA-approved complementary in vitro diagnostic test for use in the detection of PD-L1 expression in formalin-fixed, paraffin-embedded melanoma tissue.

In addition, the FDA approved Bristol-Myers Squibb's Opdivo (nivolumab) in combination with Yervoy (ipilimumab) for the treatment of patients with unresectable or metastatic melanoma, regardless of BRAF mutational status. The approval expands the original indication for the Opdivo plus Yervoy regimen for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma to include all patients, regardless of BRAF mutational status. The FDA also expanded the use of Opdivo as a single agent to include previously untreated BRAF mutation-positive advanced melanoma patients. These expanded indications are approved under accelerated approval based on progression-free survival. Continued approval for these indications may be contingent on verification and description of clinical benefit in confirmatory trials.

Dako selected Quest Diagnostics to validate and ensure the PD-L1 IHC 28-8 pharmDx test would be widely available to physicians and patients upon FDA approval through qualified lab providers. This is the third service that Quest has made available based on the Dako PD-L1 test through an expedited process related to FDA approval of an immunotherapy.

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