



Quest Diagnostics Expands Dako's PD-L1 IHC 28-8 Complementary Test to Include Melanoma

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Third offering in Quest's precision medicine menu for oncology immunotherapies

MADISON, N.J., Jan. 25, 2016 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced it will offer clinical laboratory testing using the PD-L1 IHC 28-8 pharmDx qualitative test from Dako, an Agilent Technologies company. Earlier today, Dako announced the U.S. Food and Drug Administration (FDA) approved the complementary in vitro diagnostic test for use in the detection of PD-L1 expression in formalin-fixed, paraffin embedded (FFPE) 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 + 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 upon verification and description of clinical benefit in confirmatory trials.

The PD-L1 IHC 28-8 pharmDx complementary test is distinct from companion diagnostics, which are essential for safe and effective use of a drug. Biomarker testing is not required for the OPDIVO + YERVOY Regimen or OPDIVO as a single-agent, but it may provide additional information for physicians regarding the use of OPDIVO.

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. Quest expects to make the test service available for order in the United States beginning February 1. This is the third service that Quest Diagnostics has made available based on the Dako PD-L1 test through an expedited process related to FDA approval of an immunotherapy.

"Our experience with Quest gives us confidence in their ability to provide an exceptional test service based on our PD-L1 test," said Henrik Winther, vice president and general manager, companion diagnostics, Agilent. "Quest has unprecedented reach and relationships with a great many physicians and hospitals, including leading cancer centers. This capability will facilitate broad, rapid access for patients who can benefit from this technology."

"Immunotherapies will be increasingly important to cancer treatment, and we expect FDA approval of other oncology immunotherapies in the coming years," said Christopher Fikry, M.D., general manager, oncology, Quest Diagnostics. "Quest's expertise, scale and collaborations with top organizations such as Dako and Bristol-Myers Squibb position us to provide companion and complementary diagnostic test services for immunotherapies on a scale other providers can't match. In doing so, we aim to play our part in giving individuals struggling with cancer better reason for hope."

In 2015, an estimated 73,870 new melanomas were diagnosed and 9,940 individuals died of the disease, according to the American Cancer Society, making it the most deadly of skin cancers.

Quest Diagnostics is a leading diagnostics services provider in oncology and genetics. Covering the breadth of diagnostic services, from screening and diagnosis to treatment selection and monitoring recurrence, the company's expertise spans several cancers, including breast, thyroid, skin, non-small cell lung cancer, colorectal, prostate, and cervical, among others. The company provides several immunohistochemistry testing services, including those for non-small cell lung cancer and metastatic melanoma.

About Quest Diagnostics

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 45,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. www.QuestDiagnostics.com.

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