



## Quest Diagnostics Introduces Dako's PD-L1 Complementary Diagnostic Test to Support Bristol-Myers Squibb's OPDIVO® Anti-PD-1 Therapy for Non-squamous Non-small Cell Lung Cancer

October 9, 2015

**The new Quest test service is based on the first FDA-approved complementary diagnostic**

MADISON, N.J., Oct. 9, 2015 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced that it now provides clinical laboratory testing using the PD-L1 IHC 28-8 pharmDx immunohistochemistry test, available through Dako, an Agilent Technologies company.



Today, the U.S. Food and Drug Administration (FDA) approved Bristol-Myers Squibb's OPDIVO® (nivolumab) for the treatment of patients with previously treated metastatic non-small cell lung cancer (NSCLC). The approval expands the indication for OPDIVO® to include both previously treated squamous and non-squamous NSCLC.

Also today, the FDA approved the PD-L1 IHC 28-8 pharmDx as a complementary diagnostic for non-squamous non-small cell carcinoma. The Dako test was used to assess PD-L1 expression in the Phase 3 CheckMate 057 trial, in which OPDIVO® demonstrated superior overall survival in patients with previously-treated metastatic non-squamous NSCLC compared to chemotherapy. These complementary tests are distinct from companion diagnostics, which are essential for safe and effective use of a drug. Biomarker testing is not required for OPDIVO®; but it may provide additional information for physicians and inform patient dialogue

Physicians in the United States may order the PD-L1 IHC 28-8 pharmDx test service directly from Quest Diagnostics. As one of the first labs to have the assay validated and available through early work with Dako, Quest mobilized to offer the test service in tandem with the expected FDA approval of OPDIVO®, a process that can take weeks. The test is now available to physicians in all 50 states.

"Quest's leadership in cancer diagnostics, and their reach to half the physicians and hospitals in the United States, makes it the right partner to ensure wide access to the PD-L1 IHC 28-8 pharmDx test," said Henrik Winther, Agilent vice president and general manager, Companion Diagnostics.

"Lung cancer is the leading cause of cancer-related deaths, yet has traditionally been very difficult to combat with conventional therapies. The addition of the PD-L1 test to Quest's oncology diagnostics arsenal will give physicians greater understanding of treatment expectations with OPDIVO®, a new treatment option, and helpful information to communicate to patients," said Christopher Fikry, M.D., general manager, oncology, Quest Diagnostics. "We believe the addition of Dako's nivolumab test to our extensive cancer test menu will give clinicians greater insight on the individual patient."

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, non-small cell lung cancer, colorectal, prostate, and cervical, among others. The company provides several NSCLC testing services, including molecular testing of mutations in the EGFR, KRAS and ALK genes associated with individual response to certain chemotherapies.

According to the American Cancer Society, more than 221,200 people are expected to be diagnosed with lung or bronchus cancer in the U.S. in 2015, and 158,000 may die, making it the leading cause of cancer-related death in the United States. NSCLC, the most common form of lung cancer, is relatively resistant to chemotherapy and radiation therapy.

### About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic information services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic information services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at [QuestDiagnostics.com](http://QuestDiagnostics.com). Follow us at [Facebook.com/QuestDiagnostics](https://www.facebook.com/QuestDiagnostics) and [Twitter.com/QuestDX](https://twitter.com/QuestDX).

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