Quest Diagnostics Introduces Dako's PD-L1 Companion Diagnostic for KEYTRUDA®, Merck's Anti-PD-1 Therapy for Metastatic Non-Small Cell Lung Cancer Whose Tumors Express PD-L1 with Disease Progression On or After Platinum-Containing Chemotherapy

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Testing by Quest will advance precision medicine by helping to identify patients who may benefit from new oncology immunotherapy

MADISON, N.J., Oct. 2, 2015 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced that it will provide clinical laboratory testing using the PD-L1 IHC 22C3 PharmDx™ immunohistochemistry companion diagnostic.

Earlier today, the U.S. Food and Drug Administration (FDA) approved Merck's KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy at a dose of 2mg/kg every three weeks, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA. In aligned actions today, the FDA granted pre-market approval to Dako North America, Inc., an Agilent Technologies company, for the PD-L1 IHC 22C3 PharmDx test for NSCLC.

"We believe that testing for the PD-L1 biomarker can provide important information that will help guide treatment decisions for patients with metastatic non-small cell lung cancer," said Frank Clyburn, president, Merck Oncology. "We are pleased that Quest Diagnostics is making PD-L1 testing available to physicians and patients across the country given their experience and capabilities in oncology diagnostics."

Physicians in the United States may order PD-L1 IHC 22C3 pharmDx testing 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 PD-L1 IHC 22C3 pharmDx test service in tandem with the expected FDA approvals, a process that can take weeks. As a result of these efforts, physicians will be able to order the Quest service nationally beginning today.

"Quest's partnership and expertise is critical to the successful introduction of our PD-L1 IHC 22C3 pharmDx test to physicians and patients," said Henrik Winther, Agilent vice president and general manager of the CDx Division "We're proud to work with a leader of Quest's caliber in cancer and companion diagnostics. Through this relationship, many more people may be able to access and benefit from our new offering."

PD-L1, also called programmed death ligand 1, is a protein expressed on many types of cells, including some cancer cells. Under normal conditions, the interaction of PD-L1 with another protein, called programmed death receptor-1 (PD-1), serves as an important immune system checkpoint, keeping the immune system in balance and preventing the body from attacking its own cells when inflammation or an infection is present. When cancerous tumors express PD-L1, however, they are able to escape detection and destruction by cytotoxic T-cells – a type of cancer-killing immune cell – allowing the tumor to survive and grow. Tumor PD-L1 expression has been observed at varying levels across many tumor types, including breast, lung and bladder cancer.

"Companion diagnostics are the backbone of precision medicine. Today's addition of PD-L1 testing to our oncology menu underscores our mission to provide clinicians with innovations in precision medicine that may improve clinical care and patient outcomes," said Christopher Fikry, M.D., general manager, oncology, Quest Diagnostics. "By aiding the selection of KEYTRUDA therapy, our new PD-L1 testing service will deliver diagnostic insight to potentially help more patients fight back against the most prevalent form of lung cancer."

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. Follow us at Facebook.com/QuestDiagnostics and Twitter.com/QuestDX.

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