PD-L1 Testing Update

Hematogenix Announces the Recognition by Merck & Co. as One of the National Reference Laboratories Offering PD-L1 Testing for KEYTRUDA

Hematogenix Laboratory Services (Hematogenix®) Tinley Park, IL, Jan. 17, 2017- an industry leader in the field of integrated pathology services for drug development and a leader in immune-oncology testing and integrated pathology services for drug development, announces the inclusion by Merck & Co., Inc. as one of the national reference laboratories offering the U.S. Food and Drug Administration (FDA)-approved PD-L1 companion diagnostic assay PD-L1 IHC 22C3 pharmDx for KEYTRUDA®.

Hematogenix announced in 2016 the availability of the test through Dako's PD-L1 IHC 22C3 pharmDx kit. The company's comprehensive PD-L1 offering includes all four commercially available clones offered by Dako and Ventana as well as the availability of EFGR and ALK mutation testing.

In October 2016, the FDA approved KEYTRUDA, 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.

This is the first FDA approval of a checkpoint inhibitor for first-line treatment of lung cancer. This approval also expands the indication in second-line treatment of lung cancer to include all patients with PD-L1-expressing NSCLC.

Hematogenix continues to support Merck's newest indications by reporting PD-L1 results consistent with the new FDA guidelines which include:

- **No PD-L1 Expression** (Tumor Proportion Score) [TPS] less than 1%)
- **Expression** (TPS greater than or equal to 1%)
- **High PD-L1 Expression** (TPS greater than or equal to 50%).

"By providing broad access to high quality PD-L1 testing, we will continue to help our oncology doctors identify the most appropriate treatment options for their patients." Hytham Al-Masri, MD, Medical Director/CEO goes on to state, "we support our pharma clients globally by offering these assays in both our US and European locations." Hematogenix announced in December 2016 that its Alderley Park, UK facility was awarded College of American Pathologists (CAP) accreditation.

About Hematogenix

Hematogenix a CAP/CLIA-certified laboratory with board-certified clinical, anatomic and research pathologists who provide consultation and guidance for all aspects of the company's pharma and diagnostic services. Hematogenix offers an array of biomarker development and testing services which navigate the complexities of human subject clinical trials. Hematogenix provides logistics management of sample procurement, distributes collection kits, and contributes to standards and procedures required for initiating a clinical trial. Learn more about Hematogenix's comprehensive biomarker development and testing services at www.hematogenix.com.

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