PERSONAL GENOME DIAGNOSTICS REPORTS POSITIVE DATA ON UTILITY OF LIQUID BIOPSY TESTING IN SMALL CELL LUNG CANCER PATIENTS

Data Presented at Precision: Lung Cancer World R&D Summit Confirms Accuracy of Mutation Detection Using Patient Plasma

BALTIMORE, MD, September 14, 2016 – Personal Genome Diagnostics Inc. (PGDx), a leading provider of advanced cancer genome testing products and services, today announced that data from a collaborative effort with Takeda Pharmaceuticals to assess the feasibility of liquid biopsy genomic testing for cancer drug development will be presented today at the 2016 Precision: Lung Cancer World R&D Summit in Boston, Massachusetts.

The data are from a single center, prospective study conducted by Takeda in collaboration with Drs. Charu Aggarwal and Corey Langer at the University of Pennsylvania, Janssen Diagnostics (Veridex) and PGDx in patients with advanced small cell lung cancer (SCLC). SCLC, which comprises about 15% of lung cancer cases, is an aggressive cancer with poor prognosis. Patients are typically refractory to chemotherapy after initial treatment, so new therapies are urgently needed. Since SCLC is rarely treated by surgery, tumor tissue specimens are often not available, and genomic analysis to help guide diagnosis and treatment must rely on DNA sourced from patient blood or plasma.

In the study, PGDx applied its PlasmaSELECT™ targeted panel to profile DNA from 12 relapsed SCLC patients using both circulating cell-free DNA (ctDNA) and DNA sourced from circulating tumor cells (CTCs). The cell-free DNA was extracted from plasma and prepared using proprietary methods that accommodate low abundance samples. The samples were processed using a proprietary capture method with unique barcoding DNA molecules and high coverage next-generation sequencing that allowed tumor specific (somatic) mutations, amplifications and translocations to be identified with high sensitivity and specificity.

The profiling identified important genetic alterations known to be associated with SCLC, as well as a number of mutations that were not. Importantly, in most cases the same mutations were identified from the ctDNA and CTC samples in the PGDx analysis and in a parallel analysis using a custom panel developed by Takeda. The PGDx data also showed good concordance with analyses from other sample types. Initial results of the study were presented by Huifeng Niu, PhD, Director, Translational and Biomarker Research at Takeda, at Biomarkers & Diagnostics World Congress 2016.

Mark Sausen, PhD, Vice President of Research and Development at PGDx commented, “The results of this study to profile DNA from the plasma of relapsed SCLC patients suggest that liquid biopsy approaches using ctDNA and CTCs can be employed to monitor disease progression and inform treatment options. They also may provide valuable tools for identification of prognostic, predictive and resistance biomarkers to help guide clinical research and, ultimately, patient care.”

PGDx Chief Executive Officer Doug Ward added, “This collaboration is an excellent example of our commitment to working in partnership with leading biopharmaceutical companies such as Takeda to apply our strength in liquid biopsies to identify relevant prognostic and predictive biomarkers in cancer patients. The goal is to facilitate and empower our partners’ ability to identify the most appropriate clinical population who can benefit from new targeted therapies.”

“The liquid biopsy testing performed by the PGDx platform serves patient needs through less invasive characterization of their cancer and the ability to monitor therapeutic responses through longitudinal blood sampling that is not possible with tumor biopsies,” said Andrew Dorner, PhD, Head of Translational and Biomarker Research at Takeda. “In depth patient characterization at the genomic level also allows reverse

translation of clinical findings to future drug development efforts. Takeda is committed to providing patients with the best possible care by innovation in the clinic through partnerships with companies like PGDx."

PGDx offers a complete range of cancer genome analysis tools, including exome and targeted approaches for tissue specimens, targeted approaches for plasma samples and a variety of custom tissue and plasma-based options designed to address the specific research needs of cancer researchers and drug developers. It was established in 2010 by researchers from Johns Hopkins University who are pioneers in cancer genome sequencing and liquid biopsy technologies. Under the leadership of founders Drs. Luis Diaz and Victor Velculescu, the company has achieved consistent growth by successfully commercializing novel clinical and investigational products and services for researchers, drug developers, molecular testing laboratories and physicians and patients. PGDx's service offerings for researchers and testing labs are complemented by the clinical services it provides through its CLIA-certified laboratory.

Sunita Badola, Director, Functional Genomics at Takeda, will present, "A pilot study to assess prognostic and predictive relevance of circulating tumor DNA and circulating tumor cells in patients with advanced small cell lung cancers," on September 14, 2016 at 1:30pm ET at the Precision: Lung Cancer World R&D Summit. For more information, visit http://precisionlungcancer.com/.

About Personal Genome Diagnostics
Personal Genome Diagnostics (PGDx) advances the frontiers of cancer medicine through innovative genomic technologies for oncology researchers, drug developers, clinicians and patients. The expert team at PGDx draws on a deep understanding of cancer biology, extensive experience in cancer genomics and clinical oncology, and the company's distinctive technologies. These novel technologies precisely identify and characterize unique genomic alterations in tumors. PGDx is working toward broad patient access to its genomic approaches, through a CLIA-certified facility providing comprehensive genomic services, as well as a technology transfer solution enabling other molecular laboratories to easily internalize testing. For additional information, visit personalgenome.com.

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