Personal Genome Diagnostics' TMB Analysis Used in Groundbreaking NEJM Study Showing Promising Checkpoint Inhibitor Efficacy in Early Stage Lung Cancer

—PGDx's "Gold Standard" Tumor Mutation Burden (TMB) Whole Exome Analysis Helped Identify Early Stage NSCLC Patients Most Likely to Benefit from Immuno-Oncology Treatment Before Surgery—

BALTIMORE, MD, April 19, 2018 – Personal Genome Diagnostics Inc. (PGDx) today reported that its whole exome analysis platform contributed to an important new study published in the *New England Journal of Medicine* (NEJM) showing promising efficacy for a leading checkpoint inhibitor in early stage lung cancer.[1] The study also showed that patients who had higher tumor mutation burden (TMB) according to the PGDx analysis had better responses to the checkpoint inhibitor than those with lower tumor mutation loads. The study was conducted by cancer researchers from Johns Hopkins University, including PGDx co-founder Victor Velculescu, MD, PhD, and the Memorial Sloan Kettering Cancer Center (MSK). Earlier this year, PGDx announced an agreement with MSK for developing, registering and commercializing products and services that include tumor mutation burden biomarker status.

The NEJM study reported that non-small cell lung cancer (NSCLC) patients who received the anti-PD-1 agent nivolumab before undergoing surgery for their cancer experienced fewer relapses than patients who did not. The nivolumab-treated patients also showed signs of anti-tumor immunity stimulated by the immuno-oncology therapy. Importantly, the study showed a direct correlation between TMB and checkpoint inhibitor response--patients with higher mutation burden scores as measured by the PGDx platform had a better response to nivolumab—the more tumor mutations, the better the response. TMB scores were even better predictors of response to nivolumab than measurements of PD-1 itself.

John Simmons, PhD, Director of Translational Science at PGDx, commented, "We are proud that our pioneering work in whole exome analysis has made our platform a standard for many in the field of oncology. The analysis generated using the PGDx exome platform (shown in Figure 3 in the NEJM study) shows a striking correlation between tumor mutation load and response to immune checkpoint blockade. We believe that the high-quality mutation detection approach developed at PGDx, including our proprietary VariantDx™ bioinformatics pipeline, contributed to the strength of the results."

Dr. Simmons added, "This study also highlights the clinical relevance of TMB, even in early stage disease prior to therapy. Whole exome analysis has been the 'gold standard' driving the field's understanding of how mutation load affects clinical response to checkpoint blockade, but it isn't currently practical for routine clinical use. Our ongoing initiative to translate our expertise and research applications into standardized IVD testing products for measuring TMB and other cancer biomarkers is intended to ensure wide accessibility and use of these tools by drug developers and physicians."

"This study is an excellent example of how the advanced scientific work of our distinguished founders gives us the opportunity to contribute to groundbreaking cancer research while reinforcing our credibility with our industry partners," said Doug Ward, CEO of Personal Genome Diagnostics. "Our leading VariantDx bioinformatics analysis pipeline that informed this study and fuels our PGDx assays has allowed PGDx to be a leader in immuno-oncology testing. We look forward to working with our growing network of partners to deliver accurate, accessible diagnostic tests that indicate the most effective therapies for patients--an essential part of the genomic revolution that is transforming cancer treatment."

PGDx has expertise in cancer genome analysis ranging from sample preparation and sequencing to data interpretation and analysis. The company uses next-generation sequencing (NGS) and its proprietary algorithms to identify alterations in complex cancer genomics and has developed novel technologies for non-invasive approaches to cancer diagnostics. PGDx is also developing and will commercialize a portfolio of clinically validated, regulated tissue and liquid biopsy cancer tests, enabling worldwide access to standardized NGS testing.

1 – Neoadjuvant PD-1 Blockade in Resectable Lung Cancer, P.M. Forde, J.E. Chaft, K.N. Smith, V. Anagnostou, T.R. Cottrell, M.D. Hellmann, M. Zahurak, S.C. Yang, D.R. Jones, S. Broderick, R.J. Battafarano, M.J. Velez, N. Rekhtman, Z. Olah, J. Naidoo, K.A. Marrone, F. Verde, H. Guo, J. Zhang, J.X. Caushi, H.Y. Chan, J.-W. Sidhom, R.B. Scharpf, J. White, E. Gabrielson, H. Wang, G.L. Rosner, V. Rusch, J.D. Wolchok, T. Merghoub, J.M. Taube, V.E. Velculescu, S.L. Topalian, J.R. Brahmer, and D.M. Pardoll, New England Journal of Medicine, April 16, 2018

About Personal Genome Diagnostics

Personal Genome Diagnostics (PGDx) empowers the fight against cancer by unlocking actionable information from the genome. We are committed to developing a portfolio of regulated tissue-based and liquid biopsy genomic products for laboratories worldwide. PGDx was established by internationally-recognized cancer researchers Dr. Luis Diaz and Dr. Victor Velculescu, who are pioneers in the application of innovative genomic technologies for drug development and clinical practice. For additional information, visit PersonalGenome.com.

###

Contacts

PGDx Corporate:
Megan Bailey
Vice President, Marketing
520 820-8710
mbailey@pgdx.com

Media:
Barbara Lindheim
BLL Partners LLC
212 584-2276
blindheim@bllbiopartners.com