

## **Personal Genome Diagnostics Collaborates with Merck on Global Clinical Trial Evaluating Response to Dual Biomarker Directed Precision Oncology Combination Therapy**

— *Study uses PGDx elio™ tissue TMB assay* —

**BALTIMORE, MD, January 3, 2019** – Personal Genome Diagnostics Inc. (PGDx), a leader in cancer genomics, today reported that its 500+ gene pan-cancer tumor profiling tissue assay is being used in Merck's Phase 2 precision oncology KeyImPaCT study of biomarker-directed, pembrolizumab-based combination therapy for advanced non-small-cell lung cancer (NSCLC) (KEYNOTE-495). This study will investigate the utility of biomarker-based triage for study participants with previously untreated advanced NSCLC. The PGDx elio™ tissue complete assay is being used during the enrollment process for the analysis of tumor mutational burden (TMB) status.

Study participants within groups defined by a biomarker-based classifier (gene expression profile [GEP] and TMB) will be randomized to receive pembrolizumab in combination with MK-4280 or lenvatinib. The study will involve more than 70 clinical sites world-wide.

"We are proud to collaborate with Merck on this trial. Merck is a leader in immune-oncology and we view their selection of PGDx as a testament to our capabilities around TMB," said Doug Ward, Chief Executive Officer at PGDx. "With the kitted approach for the PGDx elio portfolio, we aim to expand patient access to comprehensive, local genomic testing and reduce turn-around time for results that inform critical treatment decisions for patients worldwide."

PGDx provides genomic solutions from biomarker discovery to companion diagnostic development through its CAP/CLIA certified laboratory and is developing a portfolio of regulated tissue-based and liquid biopsy genomic products to enable local next-generation sequencing (NGS) testing in laboratories worldwide.

### **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 researchers from Johns Hopkins University who are pioneers in cancer genome sequencing and liquid biopsy technologies. For additional information, visit [PersonalGenome.com](http://PersonalGenome.com).

###

### **Contacts**

PGDx Corporate:  
Megan Bailey  
Vice President, Marketing  
520-820-8710  
[m Bailey@pgdx.com](mailto:m Bailey@pgdx.com)

W2O Group:  
Peter Duckler  
Director, Media  
773-343-3068  
[pduckler@w2ogroup.com](mailto:pduckler@w2ogroup.com)