Personal Genome Diagnostics Receives Investigational Device Exemption Approval from the FDA to Support Merck's Precision Oncology Trial

— PGDx elio™ tissue complete assay will be used to identify candidates for pembrolizumab-based combination therapy —

BALTIMORE, MD, December 4, 2019 – Personal Genome Diagnostics Inc. (PGDx), a leader in cancer genomics, received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) for the use of the company's elio™ tissue complete assay in a Merck trial of pembrolizumab-based combination therapy. The PGDx™ elio assay will be used during the trial to analyze genomic markers to direct patient enrollment and stratification.

"We're pleased with the FDA's decision to approve PGDx's elio™ tissue complete assay for this trial, as it validates the robustness of the test and reinforces the role of diagnostic biomarkers in investigating treatment strategies for patients living with cancer," said Doug Ward, Chief Executive Officer at PGDx. "Further, Merck's selection of this assay for use in their trials underscores its value and performance in ongoing oncology research."

The PGDx elio™ tissue complete panel is a 500+ gene test for somatic alterations that detects single nucleotide variants (SNVs), small insertion/deletions, amplifications, rearrangements, microsatellite instability (MSI) and tumor mutation burden. 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 improving clinical insight, speed of results, and healthcare economics by delivering 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 www.PersonalGenome.com.

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