

International Clinical Trial Utilizes Personal Genome Diagnostics' Liquid Biopsy Assay to Enroll Patients based on POLE/POLD1 status as a Predictor of Response to Immunotherapy

— Study examines PGDx technology as an innovative, non-invasive approach with the potential to reduce need for tumor biopsies —

BALTIMORE, MD, October 9, 2018 – Personal Genome Diagnostics, Inc. (PGDx), a leader in cancer genomics and pioneer in liquid biopsy, today reported that its non-invasive, pan-cancer plasma assay is being used in an important new clinical trial, *Nivolumab, Ipilimumab in Patients With Hyper Mutated Cancers Detected in Blood* (NIMBLE), led by the Cancer Research Institute (CRI) and Canadian Cancer Trials Group (CCTG). In part, the trial will explore the use of PGDx's liquid biopsy assay to confirm POLE and POLD1 mutations in solid tumors and to investigate whether those tumor types are responsive to immunotherapy.

"We've begun to understand that tumors with gene mutations like POLE and POLD1 have a high mutational burden and are investigating whether patients with this mutation may have better response and improved survival outcomes when treated with immunotherapy," said John Simmons, PhD, Director of Translational Medicine at Personal Genome Diagnostics. "We also know that many advanced cancer patients are often unable to provide tissue samples, which can limit the ability to use genomic testing to help guide their treatment decisions. We're excited to collaborate on this innovative study."

The study will evaluate the efficacy and safety of nivolumab (anti-PD-1) alone and in combination with ipilimumab (anti-CTLA-4) in patients with POLE and POLD1 mutations and will collect both blood and tumor tissue samples from patients to look at correlation between mutations detected in a tumor tissue sample and those detected from a blood test. The study will open in centers in the U.S. and Canada soon. Nivolumab and ipilimumab have well characterized safety profiles.

"This clinical trial exemplifies our commitment to use our expertise in genomic testing to inform important cancer research and ensure that we can deliver accurate, accessible diagnostic tests to our industry partners and physicians," said Doug Ward, Chief Executive Officer at PGDx. "We view this collaboration as a demonstration of our leadership in liquid biopsy innovation and we look forward to continued partnership on non-invasive tumor profiling to make genomic testing more usable and accessible for patients globally."

PGDx provides 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 for 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.

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