Personal Genome Diagnostics Receives FDA Clearance for PGDx elio™ tissue complete, the First Comprehensive Genomic Profiling Diagnostic Kit for Oncology

PGDx elio™ tissue complete is the industry's first and only clinical next-generation sequencing (NGS) diagnostic kit for comprehensive tumor profiling that is FDA-cleared for use in labs across the country

PGDx elio™ tissue complete increases patient access to precision-based comprehensive genomic profiling

BALTIMORE, MD, April 27, 2020 – Personal Genome Diagnostics Inc. (PGDx), a leader in cancer genomics, announced today that the company has received market clearance from the U.S. Food and Drug Administration (FDA) for PGDx elio™ tissue complete, a comprehensive diagnostic kit that can be used by molecular laboratories to perform genomic profiling of cancer in a more efficient, reliable, and accurate manner. By automating the data analysis process, which is incorporated in the cleared product, PGDx is enabling the scalability of precision medicine in healthcare systems across the country.

"Nearly 80% of patients aren't getting the clinical insights they need to inform their treatment path, or they aren't being tested in a window of time that makes a difference in determining their care," said Megan Bailey, Chief Executive Officer, PGDx. "PGDx elio tissue complete responds to this unmet need by bringing genomic cancer testing of the highest quality directly to healthcare providers. Since the founding of our company we have been united in our mission to empower the fight against cancer, and an integral part of that is establishing standardized testing as a core element of patient care. Today is an incredible milestone for us, but more importantly for the millions of people living with cancer."

PGDx elio tissue complete detects single nucleotide variants (SNVs) and small insertions and deletions (indels) in 500+ genes, select amplifications and translocations, and genomic signatures including microsatellite instability (MSI) and tumor mutation burden (TMB). Collectively, the information from this diagnostic kit is intended for use by healthcare professionals to help tailor clinical management for patients based on their tumor's unique genomic profile in accordance with professional guidelines. The broad genomic profiling assay includes biomarkers to help inform the use of targeted cancer therapies and immunotherapies and can help oncologists identify patients for clinical trial participation. This FDA clearance was supported by a magnitude of data that demonstrates robustness and consistency of performance across multiple lab sites, and accuracy data across all variant classes in clinical samples from 35 tumor types.

"There has not, until this point, been one standardized test for all kinds of cancer that any lab across the country can perform," said Dr. Pranil Chandra, Chief Medical Officer of Genomic and Clinical Pathology Services, PathGroup, an early collaborator for PGDx elio tissue complete. "With this clearance, labs across the country will for the first time have an option for a regulated, standardized test that examines a broad view of cancer pathways and genomic signatures across advanced cancers. PGDx elio testing features automated bioinformatics that ensures consistent results and quality of testing, resulting in fast and reliable clinical insights to enable oncologists to match patients with the best therapies to fight their cancer."

"Personal Genome Diagnostics is pioneering an integrated healthcare ecosystem that furthers the availability and opportunities of precision medicine," said Dr. Michael Hanbury, Chief Operating Officer, PathGroup. "Developing insights into genomic drivers of cancer can provide physicians expanded understanding of patient-specific tumor genetics and improve targeted therapies to save lives and improve outcomes. This approval demonstrates the benefits of focused collaborative efforts between medical device manufacturers and pathologists to advance the diagnosis and treatment for thousands of patients with advanced tumors. We are pleased to partner with PGDx and offer this new test to our community of clients, physicians and patients."

PGDx elio™ tissue complete

PGDx elio™ tissue complete is an FDA-cleared diagnostic kit and accompanying software for molecular labs that provides comprehensive genomic profiles of all solid tumors. PGDx elio tissue complete detects single nucleotide variants (SNVs) and small insertions and deletions (indels) in 500+ genes, select amplifications and

translocations, and genomic signatures including microsatellite instability (MSI), and tumor mutation burden (TMB). Designed to be used locally at the lab of choice, PGDx elio testing and automated bioinformatics ensures both consistency and quality of testing regardless of location.

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 health systems 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.

About PathGroup
PathGroup is a premier provider of anatomic, clinical and molecular pathology services in the United States. Privately held and physician-centric, PathGroup works seamlessly with customers to provide superior diagnostic services – a vital link in the cycle of patient relationships. PathGroup uses the latest in proprietary and industry standard technology to deliver fast, accurate results. The company provides clients with the highest quality of services available, consistently exceeding the expectations of physicians, employees, payers, and most importantly, patients. One Lab; Total Service. PathGroup is owned by Pritzker Private Capital along with management. For more information, visit www.pathgroup.com.

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