Personal Genome Diagnostics CE Marks PGDx elio™ Tissue Complete Assay

--- PGDx elio™ tissue complete will empower local insight for oncology by providing timely, actionable genomic information to inform clinical decision making for cancer patients ---

BALTIMORE, MD, Sept 25 – Personal Genome Diagnostics Inc. (PGDx), a leader in cancer genomics, today announced that it has applied the CE mark to the PGDx elio™ tissue complete assay. This milestone advances PGDx's vision to bring comprehensive genomic profiling to molecular labs globally, and allows PGDx to provide greater access to precision medicine for cancer patients in the European Union (EU).

"We're pleased to bring these comprehensive, regulated genomic panels to the EU and look forward to showcasing the PGDx elio assays at the upcoming European Society for Medical Oncology Congress in Barcelona, Spain," said Doug Ward, Chief Executive Officer at PGDx. "The application of the CE mark to the PGDx elio™ tissue complete assay is an important step forward in expanding patient access to tools that can help personalized cancer care. With this assay, physicians throughout Europe will be able to secure specific, actionable information that can help them make improved treatment decisions."

The PGDx elio tissue complete panel is a 507-gene test for somatic alterations that detects single nucleotide variants (SNVs), small insertion/deletions (indels), amplifications, rearrangements, microsatellite instability (MSI) and tumor mutation burden (TMB). The use of TMB and MSI for the identification of cancer patients whose tumors may respond to immune checkpoint inhibitor therapy has recently been investigated in clinical trials (TMB) and approved (MSI) by the U.S. Food and Drug Administration (FDA).

CE marking indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). With CE marking of both elio plasma resolve and elio tissue complete, PGDx aims to provide a new standard of care for cancer patients, with regulated comprehensive Next-Generation Sequencing (NGS) panels that enable faster delivery of clinical insights to physicians.

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 www.PersonalGenome.com.

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