Personal Genome Diagnostics' PGDx elio™ plasma resolve Receives Breakthrough Device Designation from FDA

— PGDx Developing In-Vitro Diagnostic Test that Detects MSI Status in Plasma as an Aid in Selecting Cancer Patients For Certain Immunotherapies

BALTIMORE, MD, July 17, 2018 – Personal Genome Diagnostics Inc. (PGDx), a leading cancer genomics company and pioneer in liquid biopsy, today announced that PGDx elio™ plasma resolve has received Breakthrough Device designation from The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA).

PGDx elio™ plasma resolve is a qualitative in vitro diagnostic test that uses targeted high throughput, parallel-sequencing technology to detect single nucleotide variants (SNVs), small insertion/deletions (indels), amplifications, rearrangements, and microsatellite instability (MSI) in a broad multi-gene panel in circulating cell-free DNA (cfDNA) isolated from plasma samples. The FDA granted breakthrough designation based on the assay's ability to detect MSI status in plasma as an aid in selecting patients for certain therapies.

Breakthrough Device designation is intended to help give patients timely access to medical devices that provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions by expediting their development, assessment and review. Breakthrough Device designation was granted to PGDx elio™ plasma resolve based on response rate, progression free survival, and overall survival data, which showed that PGDx elio™ plasma resolve may help patients who are unable to provide tissue samples, but could benefit from genomic testing.

"We are excited about what Breakthrough Device designation for PGDx elio™ plasma resolve will mean for people with cancer," said Doug Ward, Chief Executive Officer of PGDx. "If approved, this test could be the first liquid biopsy test that can be kitted and run in laboratories worldwide and is an important advancement for patients who cannot give tissue samples. As a leader in liquid biopsy innovation, our goal is to deliver these tests to clinicians locally and expand patient access to leading scientific advances in medicine."

"This breakthrough designation is a continuation of our leadership with MSI," said John Simmons, PhD, Director of Translational Science and Diagnostics. PGDx was the first CAP/CLIA lab to offer MSI testing with NGS and the first to offer MSI testing in plasma. We're now focused on bringing these innovative technologies to patients globally by empowering clinicians with actionable information about a patient's cancer that can change the course of clinical therapy and, ultimately, improve outcomes."

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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