Personal Genome Diagnostics CE Marks Liquid Biopsy Test

— PGDx elio™ plasma resolve liquid biopsy panel brings a local, non-invasive, clinical Next-Generation Sequencing (NGS) solution to Europe —

BALTIMORE, MD, March 14, 2019 – Personal Genome Diagnostics Inc. (PGDx), a leader in cancer genomics, today announced that it has applied the CE mark to PGDx elio™ plasma resolve. It is the first kitted plasma-based NGS oncology test to have that certification, enabling greater access to genomic testing for cancer patients in Europe.

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. It encompasses several clinically actionable variants across tumor types, enabling more informed treatment decisions.

“We are extremely proud of this important milestone,” said Doug Ward, Chief Executive Officer. “Our vision is to improve clinical insight, speed of results, and health economics by delivering a portfolio of regulated tissue-based and liquid biopsy genomic products to laboratories worldwide. The CE mark of PGDx elio™ plasma resolve allows us to bring this product to Europe, providing greater access to patients who could benefit from genomic testing, particularly those who cannot provide tissue samples.”

CE certification indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). With the CE-mark, PGDx aims to advance strategic partnerships with molecular laboratory and oncology leaders in the European market to enable genomic testing closer to where patients are treated, expanding the potential of precision medicine.

The PGDx elio™ plasma resolve previously received Breakthrough Device designation from The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) in July of 2018.

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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