Personal Genome Diagnostics Announces Collaboration to Develop Plasma-Based Companion Diagnostic for Five Prime Therapeutics’ Targeted Immuno-Oncology Drug Candidate Bemarituzumab

--PGDx’s Non-Invasive Liquid Biopsy Assay Is Intended to Identify Cancer Patients Most Likely to Benefit from Treatment with Bemarituzumab (FPA144)—

BALTIMORE, MD, April 3, 2018 – Personal Genome Diagnostics Inc. (PGDx) today announced it has entered into a collaboration with Five Prime Therapeutics, Inc. (Five Prime) (Nasdaq: FPRX) to develop a plasma-based companion diagnostic assay for use with Five Prime’s first-in-class investigational drug candidate, bemarituzumab, an anti-FGFR2b antibody (also known as FPA144). The diagnostic assay will be used in Five Prime’s global registrational study (the FIGHT trial) of bemarituzumab in combination with 5-fluorouracil (5-FU), leucovorin, and oxaliplatin, as front-line treatment in patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b or have FGFR2 gene amplification.

Five Prime plans to use immunohistochemistry and circulating tumor DNA (ctDNA) tests to identify the estimated 10% of patients with gastric and gastroesophageal junction cancer who would be eligible for treatment with bemarituzumab. Under the collaboration, PGDx will develop and validate a plasma-based ctDNA in vitro diagnostic (IVD) assay to help identify patients whose tumors are FGFR2 gene-amplified and therefore eligible for treatment with bemarituzumab, initially for the Phase 3 portion of the FIGHT trial. PGDx intends to submit the assay for regulatory approval and commercialize it in the United States, Europe, Japan, China and other countries.

“We are pleased to collaborate with PGDx, a cancer genomics pioneer with a wealth of experience in accurately identifying genomic alterations in tumors,” said Aron Knickerbocker, Chief Executive Officer of Five Prime. “Patients with advanced gastric and gastroesophageal junction cancer need new treatment options. Prognosis is especially poor for patients whose tumors overexpress FGFR2b or have FGFR2 gene amplification. We believe that a targeted therapy like bemarituzumab may provide a clinical benefit in this setting and expect that PGDx’s plasma-based assay will be an accessible and flexible tool to inform patient selection.”

Bemarituzumab is an isoform-selective, humanized monoclonal antibody in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family, or amplify the FGFR2 gene. Bemarituzumab has also been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells. Clinical results to date suggest that the specificity of bemarituzumab avoids toxicities that have been seen with less selective pan-FGFR tyrosine kinase inhibitors that act on multiple FGFRs, including FGFR2.

Bemarituzumab is being evaluated in the FGFR2b Inhibition in Gastric and Gastroesophageal Junction Cancer Treatment (FIGHT) Phase 1/3 clinical trial, a global registrational study in patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b or have FGFR2 gene amplification. The Phase 3 portion of the trial is expected to begin in the second half of 2018.

Doug Ward, Chief Executive Officer of PGDx, noted: “Five Prime’s bemarituzumab has shown encouraging activity against important genetic variants of certain gastric cancers that lack effective treatment options. We welcome the opportunity to work with Five Prime to develop accurate and accessible diagnostic assays to identify patients who may benefit from this promising new drug. This collaboration reflects our commitment to provide companion diagnostics in the form of regulated, standardized IVD kits to ensure they are widely available to patients around the globe.”

Financial terms of the agreement were not disclosed.

PGDx has expertise in cancer genome analysis ranging from sample preparation and sequencing to data interpretation and analysis. The company uses next-generation sequencing and its proprietary algorithms to
identify alterations in complex cancer genomics and has developed novel technologies for non-invasive approaches to cancer diagnostics. PGDx is also developing and commercializing a portfolio of tissue and liquid biopsy clinically-validated and regulated IVD cancer tests, enabling worldwide access to PGDx technology.

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.

About Five Prime
Five Prime Therapeutics, Inc. discovers and develops innovative therapeutics to improve the lives of patients with serious diseases. Five Prime's comprehensive discovery platform, which encompasses substantially all medically relevant extracellular proteins, positions it to explore pathways in cancer, inflammation and their intersection in immuno-oncology, an area with significant therapeutic potential and the focus of the company's research and development activities. Five Prime has entered into strategic collaborations with leading global pharmaceutical companies and has promising product candidates in clinical and late preclinical development. For more information, please visit www.fiveprime.com or follow us on LinkedIn, Twitter and Facebook.

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