

Personal Genome Diagnostics Awarded National Cancer Institute Contract to Develop Novel Diagnostic for Immuno-Oncology Drugs

—Liquid Biopsy Assay Will Assess Tumor Mutational Load to Identify Those Patients Most Likely to Benefit from Treatment with Checkpoint Inhibitors—

BALTIMORE, MD, February 1, 2017 – Personal Genome Diagnostics Inc. (PGDx) today announced that it has been awarded an SBIR contract from the National Cancer Institute (NCI) for the development of a novel diagnostic to help identify patients who are most likely to benefit from treatment with immuno-oncology cancer drugs known as checkpoint inhibitors. PGDx will use the Phase 1 contract to develop MutatorDETECT™, a cost-effective liquid biopsy assay that can quantitatively assess patient tumor mutational load. PGDx expects to complete initial development of the assay this year.

Studies have shown that patients whose tumors have a large number of mutations, or high mutational load, are also likely to harbor neoantigens--new tumor-specific antigens expressed by tumor cells--that can help stimulate a robust anti-cancer immune response. These patients are accordingly more likely than those with fewer mutations to respond to treatment with checkpoint inhibitors such as Keytruda® (permbrolizumab) or Opdivo® (nivolumab).

Checkpoint inhibitors have been approved for lung, melanoma and bladder cancers that generally have higher mutational loads than other types of cancer. However, researchers are discovering that there are small subsets of patients with other types of tumors who have high mutational loads, and these patients should also be more likely to respond to immuno-oncology drugs. PGDx co-founder Dr. Luis Diaz and his co-authors were among the first to publish a prospective [study](#) demonstrating that mismatch repair (MMR)-deficient colorectal cancers, which have high tumor mutational loads, are more susceptible to treatment with immuno-oncology drugs such as Keytruda than non-MMR colorectal cancers. The availability of cost effective, non-invasive genomic testing with an assay such as MutatorDETECT would make it more feasible to identify these patients.

The new PGDx assay is a liquid biopsy that assesses tumor mutational load using cell-free tumor DNA (ctDNA) circulating in patient plasma. Existing approaches for determining tumor mutational load are costly and require the use of biopsy tissue, which is available, if at all, only at the start of treatment. Liquid biopsies allow for testing over the course of therapy to track evolving changes in mutational status.

Mark Sausen, PhD, PGDx Vice President of R&D and co-Principal Investigator for the NCI contract, commented, "Immuno-oncology drugs have shown great promise, but they are expensive and do not work for all patients. Affordable and accessible methods to identify patients likely to benefit are urgently needed. This NCI contract leverages our extensive experience and proprietary approaches for studying tumor neoantigens and developing immuno-oncology therapies, combined with PGDx's pioneering work in developing liquid biopsies for cancer genomic testing."

Dr. Sausen continued, "Over the past several years we have collaborated with pharmaceutical partners to evaluate the effects of mutational load by retrospectively applying whole exome sequencing and our ImmunoSelect™ analyses to clinical samples. This contract now gives us the opportunity to work with these partners to develop the MutatorDETECT assay to identify patients prospectively for clinical trial enrollment."

The Phase 1 NCI contract, "A Non-Invasive Approach to Assess Mutational Load in Tumors for Treatment with Checkpoint Inhibitors," covers development of the assay through early evaluation in clinical samples.

PGDx offers a complete range of cancer genome analysis tools, including exome and targeted approaches for tissue specimens, targeted approaches for plasma samples and a variety of custom tissue and plasma-based options designed to address the specific research needs of cancer researchers and drug developers.

PGDx's service offerings for researchers and testing labs are complemented by the clinical services it provides through its CLIA-certified laboratory.

About Personal Genome Diagnostics

Personal Genome Diagnostics (PGDx) advances the frontiers of cancer medicine through innovative genomic technologies for oncology researchers, drug developers, clinicians and patients. The expert team at PGDx draws on a deep understanding of cancer biology, extensive experience in cancer genomics and clinical oncology, and the company's distinctive technologies. It was established in 2010 by researchers from Johns Hopkins University who are pioneers in cancer genome sequencing and liquid biopsy technologies. Under the leadership of founders Drs. Luis Diaz and Victor Velculescu, the company has achieved consistent growth by successfully commercializing novel clinical and investigational products and services. These novel technologies precisely identify and characterize unique genomic alterations in tumors. PGDx is working toward broad patient access to its genomic approaches, through a CLIA-certified facility providing comprehensive genomic services, as well as its PROGENEUS™ technology transfer solution and in vitro diagnostic products to enable other molecular laboratories to easily internalize genomic testing. For additional information, visit personalgenome.com.

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