



PERSONAL GENOME DIAGNOSTICS HIGHLIGHTS ITS PATENT-PENDING MICROSATELLITE INSTABILITY TESTING TECHNOLOGY AS FDA APPROVES KEYTRUDA® FOR MSI TUMORS

--MSI Testing Already Incorporated in PGDx's Pan Cancer Profiling Panels Using Patent-Pending Technology Licensed from Johns Hopkins University--

-- PGDx's PlasmaSELECT™ Is the Only Liquid Biopsy Panel that Includes MSI Testing--

--Learn More about PGDx's Advanced Cancer Genomic Testing at 2017 ASCO Booth #2078--

BALTIMORE, MD, June 2, 2017 – Personal Genome Diagnostics Inc. (PGDx), a pioneer in cancer genomic testing, today highlighted its patent-pending microsatellite instability (MSI) testing technology following the U.S. Food and Drug Administration's (FDA) accelerated approval of Merck's immuno-oncology agent Keytruda® (pembrolizumab) for children and adults whose advanced solid tumors are marked by microsatellite instability (MSI). This is the first approval of a cancer drug based on the genetic make-up of the tumor rather than its location in the body. Patients will likely be tested for MSI status before receiving Keytruda under the expanded indication.

Tumors that display MSI have lost the ability to repair errors in their DNA as a result of a condition known as mismatch repair deficiency (MMR). Researchers from The Johns Hopkins University, PGDx and other institutions have shown that tumors displaying MMR deficiency and MSI are more susceptible to successful treatment with Keytruda and other immuno-oncology drugs. MSI tumors have been identified in colorectal, endometrial, gastric and other types of cancer.

"This landmark FDA approval codifies the need to determine whether cancer patients potentially eligible for immuno-oncology therapy have microsatellite instability present in their tumors," said Doug Ward, CEO of PGDx. "It is particularly fitting that the approval involves MSI, a genomic condition whose relevance to cancer therapy was first uncovered by researchers at Johns Hopkins, with assistance from researchers at PGDx. We were thrilled to license rights to the patent-pending MSI measurement technology for immuno-oncology applications developed at Johns Hopkins, and are proud to be the first to offer it in both tissue and liquid biopsy formats. PGDx is also planning to submit a tissue-based MSI assay for FDA review later this year."

PGDx's MSI testing is incorporated in the company's tissue-based [CancerSELECT® 125](#) pan cancer genomic profiling assay and its non-invasive [PlasmaSELECT™ 64](#) pan cancer assay that analyzes circulating tumor DNA in patient plasma. The company also recently received [grant funding from the National Cancer Institute](#) to advance liquid biopsy tests for determining a related biomarker known as tumor mutational burden.

PGDx was an early leader in identifying the importance of MSI, contributing to [a study](#) on MMR and immune checkpoint blockade presented at the 2015 ASCO Annual Meeting. In that study, researchers found that colorectal cancer patients who had tumors with MSI/MMR deficiency had a much greater therapeutic response to pembrolizumab. The analysis showed that cancer patients with MSI/MMR deficiency on average had more than 20 times the number of mutations in their tumors as similar patients who were not mismatch repair deficient. This finding is consistent with other studies showing that PD-1/PD-L1 checkpoint blockers are most effective against tumors containing many mutations. The study was published in the [New England Journal of Medicine](#).

"We established PGDx to advance technology invented at Johns Hopkins based on our belief that greater understanding of tumor genomics would ultimately enable more effective and less toxic treatments for cancer," noted Victor E. Velculescu, MD, PhD, a co-founder of PGDx. Dr. Velculescu also is Professor of Oncology at the Johns Hopkins University School of Medicine. "This breakthrough approval from the FDA is an important milestone in the realization of that vision. I am proud that PGDx has played a significant role in this advance and that the company will help many more patients realize the benefits of immuno-oncology approaches for cancer treatment."

PGDx representatives will be attending the 2017 ASCO Annual Meeting and are available at Booth #2078 to discuss the company's MSI testing and its complete range of cancer genome analysis tools for researchers and clinicians. Research services include 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 to patients and physicians through its CLIA-certified laboratory, including its CancerSELECT 125 pan cancer genomic profiling assay and the non-invasive PlasmaSELECT™ 64 pan cancer profiling assay, both of which include MSI testing.

About Personal Genome Diagnostics

Personal Genome Diagnostics (PGDx) is empowering the fight against cancer by unlocking actionable information from the genome 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 that precisely identify and characterize unique genomic alterations in tumors. PGDx is working toward broad patient access to its genomic technologies and products, through a CLIA-certified facility providing comprehensive genomic services, as well as a portfolio of tissue-based and liquid biopsy genomic testing products for laboratories worldwide. Privately-held PGDx is headquartered in Baltimore, MD. For additional information, visit PersonalGenome.com.

###

Contacts

PGDx Corporate:

Melody Gretz

973-598-5515

mgretz@personalgenome.com

PGDx Media

Barbara Lindheim

212-584-2276

BLL Partners, LLC

blindheim@bllbiopartners.com