# Personal Genome Diagnostics Expands Its Tumor Mutational Burden (TMB) Patent Portfolio for Cancer Immunotherapy

**BALTIMORE, MD, February 28, 2018** – Personal Genome Diagnostics Inc. (PGDx) today announced an agreement with Memorial Sloan Kettering Cancer Center (MSK) for developing, registering, and commercializing products and services that include tumor mutation burden (TMB) biomarker status. Under the terms of the licensing agreement, PGDx receives exclusive rights for the diagnostic field of use to MSK's TMB-related intellectual property discovered by Timothy Chan, Naiyer Rizvi, et.al and featured in their groundbreaking 2015 publication in Science.[1]

TMB is a biomarker that measures the number of mutations present in cancer patients' tumors. A growing body of evidence indicates that tumors with many mutations are more likely to respond to the new immuno-oncology therapies that are revolutionizing cancer treatment.

"Researchers affiliated with PGDx were instrumental in uncovering the link between tumor mutation status and response to immuno-oncology therapies, and we were among the first to include biomarkers for tumor mutation status in our tissue and liquid biopsy profiling tests," said Doug Ward, CEO of Personal Genome Diagnostics. "In 2016 we licensed co-exclusive rights to important intellectual property in this area from Johns Hopkins University and are now pleased to reinforce our IP portfolio by licensing MSK's complementary patents. We are confident that the combined patent estate adequately protects our extensive investment and development plans for our TMB-enabling tests."

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

Under the terms of the licensing agreement, PGDx has acquired exclusive rights to MSK's TMB patents for all types of genomic testing, including tissue and liquid biopsy tests, laboratory-developed tests (LDTs), standardized in vitro diagnostic (IVD) tests and companion diagnostics. Financial terms of the agreement were not disclosed.

PGDx and MSK were early contributors to understanding the importance of tumor mutation load status to immuno-oncology drug response, showing that tumors containing more mutations are more immunogenic and therefore more likely to respond well to therapies that harness the immune system to fight cancer. The newly licensed intellectual property builds on a 2015 *Science* study from MSK researchers and colleagues showing that non-small cell lung cancer patients with high TMB scores had a significantly better response to the checkpoint inhibitor pembrolizumab than those whose tumors had fewer mutations.[1]

PGDx researchers also contributed to a 2015 seminal study published in the *New England Journal of Medicine* that assessed another measure of mutation status–microsatellite instability (MSI).[2] The researchers found that cancer patients who had tumors with high MSI had a much greater therapeutic response to pembrolizumab. More recent studies have confirmed the importance of mutational status to immuno-oncology therapy response.

References:

1.Rizvi N. Hellmann M. Synder A. Mutational landscape determines sensitivity to PD-1 blockade in non–small cell lung cancer. Science. 2015 Apr 3; 348(6230): 124–128

2. Le D. Uram J. Wang H. et al. PD-1 Blockade in tumors with mismatch-repair deficiency. N Engl J Med 2015; 372:2509-2520

**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 in 2010 by researchers from Johns Hopkins University who are pioneers in cancer genome sequencing and liquid biopsy technologies. For additional information, visit pgdx.com.

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