FDA Grants Breakthrough Device Designation To Tempus' HLA-LOH Companion Diagnostic Test

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Tempus, a leader in artificial intelligence and precision medicine, today announced that the U.S. Food & Drug Administration (FDA) has granted the company Breakthrough Device Designation for its HLA-LOH assay as a companion diagnostic (CDx) test. The test uses a machine learning model to analyze sequence data produced by Tempus' FDA-approved, next generation sequencing-based xT CDx assay. It is intended to identify cancer patients with solid tumors who may benefit from treatment with specific targeted therapies when a patient's tumor has experienced allele-specific loss of heterozygosity (LOH) for specific human leukocyte antigen (HLA) Class I alleles.

"HLA-LOH provides a clear molecular distinction between cancer and non-cancer cells and is a potential biomarker for immune therapy resistance. The Tempus HLA-LOH test is intended to measure this biomarker and better understand which patients may respond to new therapies," said Kate Sasser, PhD, Chief Scientific Officer of Tempus. "This Breakthrough Device Designation from the FDA recognizes the novelty and potential clinical impact of our HLA-LOH test for this promising biomarker. HLA-LOH is of special interest for the application of cell therapy to treat solid tumors, but also has broader potential for other precision medicine approaches in oncology, including in combination with other established biomarkers. The Tempus test is being developed to identify HLA-LOH and may help optimize existing therapies and facilitate the advancement and implementation of novel and transformative treatments."

More than 90% of all yearly diagnosed cancers in U.S. patients comprise solid tumors. Many individuals afflicted by solid tumors receive late-stage diagnoses or encounter metastatic disease during relapse, leaving them with limited treatment options. Tempus' HLA-LOH test is designed to identify an emerging biomarker that can help address the unmet need for better targeted therapies for these patients.

The FDA's Breakthrough Devices Program aims to provide healthcare providers and patients with timely access to medical devices that provide more effective diagnosis or treatment of serious conditions or diseases. This program accelerates the development, assessment, and review processes, while simultaneously upholding the necessary standards for safety and effectiveness.

About Tempus

Tempus is a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare. With one of the world's largest libraries of multimodal data, and an operating system to make that data accessible and useful, Tempus provides AI-enabled precision medicine solutions to physicians to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. The goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as the company gathers more data. For more information, visit tempus.com.