NPJ Precision Oncology Publishes Tempus Study on Validation of its HLA-LOH Investigational Assay

August 8, 2024

CHICAGO--(BUSINESS WIRE)--Aug. 8, 2024-- Tempus AI, Inc. (NASDAQ: TEM), a technology company leading the adoption of AI to advance precision medicine and patient care, today announced that the validation study of its human leukocyte antigen (HLA) loss of heterozygosity (LOH) investigational assay has been published in *npj Precision Oncology*. Titled, "Detecting HLA loss of heterozygosity within a standard diagnostic sequencing workflow for prognostic and therapeutic opportunities," the study included analytical validation of an investigational test that detects HLA-LOH based on analysis of data generated from Tempus' FDA-approved, next generation sequencing-based xT CDx assay. The test uses a machine learning model to analyze sequenced data produced by Tempus' xT CDx assay to identify patients with solid tumors that have experienced allele-specific LOH for specific HLA Class I alleles and may benefit from treatment with specific, targeted therapies.

The study evaluated the test's ability to accurately detect HLA-LOH in clinical samples with >=40% tumor cells. In collaboration with A2 Biotherapeutics, Tempus analyzed data from an observational clinical trial (NCT04981119), and demonstrated the feasibility of identifying HLA-LOH patients and accruing them into prospective studies by leveraging analysis of routinely obtained clinical diagnostic data. Results support the assay's use as an investigational device for precision oncology clinical trial use.

"Tempus' HLA-LOH test is particularly significant for use in clinical trials that apply cell therapy to solid tumors, and it also has wider implications for precision medicine, including its use alongside other established biomarkers," said Kate Sasser, PhD, Chief Scientific Officer at Tempus. "As validated in this study, the HLA-LOH test may help identify patients most likely to benefit from new and exciting therapies."

In 2023, the U.S. Food & Drug Administration (FDA) granted Breakthrough Device Designation for the use of Tempus' HLA-LOH assay as a companion diagnostic test. The HLA-LOH assay is an investigational device that is not currently available for clinical use.

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.

About xT CDx

xT CDx is a qualitative Next Generation Sequencing (NGS)-based in vitro diagnostic device intended for use in the detection of substitutions (single nucleotide variants (SNVs) and multi-nucleotide variants (MNVs)) and insertion and deletion alterations (INDELs) in 648 genes, as well as microsatellite instability (MSI) status, using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens, and DNA isolated from matched normal blood or saliva specimens, from previously diagnosed cancer patients with solid malignant neoplasms.

The test is intended as a companion diagnostic (CDx) to identify patients who may benefit from treatment with the targeted therapies listed in the Companion Diagnostic Indications table in accordance with the approved therapeutic product labeling.

Additionally, xT CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with previously diagnosed solid malignant neoplasms. Genomic findings other than those listed in the Companion Diagnostic Indications table are not prescriptive or conclusive for labeled use of any specific therapeutic product.

xT CDx is a single-site assay performed at Tempus AI, Inc., Chicago, IL. For the complete xT CDx label, including Companion Diagnostic Indications table and important risk information, please visit https://www.tempus.com/resources/document-library/tempus-xt-cdx_technical-information/.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, about Tempus and Tempus' industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release are forward-looking statements, including, but not limited to, statements regarding the quality of this study; the contributions of this study to the larger scientific community, and the use of Tempus' products and services to advance clinical care for patients. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "going to," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. Tempus cautions you that the foregoing may not include all of the forward-looking statements made in this press release.

You should not rely on forward-looking statements as predictions of future events. Tempus has based the forward-looking statements contained in this press release primarily on its current expectations and projections about future events and trends that it believes may affect Tempus' business, financial condition, results of operations and prospects. These forward-looking statements are subject to risks and uncertainties related to: Tempus' financial performance; the ability to attract and retain customers and partners; managing Tempus' growth and future expenses; competition and new market entrants; compliance with new laws, regulations and executive actions, including any evolving regulations in the artificial intelligence space; the ability to maintain, protect and enhance Tempus' intellectual property; the ability to attract and retain qualified team members and key personnel; the ability to repay or refinance outstanding debt, or to access additional financing; future acquisitions, divestitures or investments; the potential adverse impact of climate change, natural disasters, health epidemics, macroeconomic conditions, and war or other armed conflict, as well as risks, uncertainties, and other factors described in the section titled "Risk Factors" in Tempus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 filed with the Securities and Exchange Commission ("SEC") as well as in other filings Tempus may make with the SEC in the future. In addition, any forward-looking statements contained in this press release are based on assumptions that Tempus believes to be reasonable as of this date. Tempus undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of this press release or to reflect new information or the occurrence of unanticipated events, except as required by law.

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