Tempus Announces the National Launch of FDA-Approved xT CDx Test

January 15, 2025

CHICAGO--(BUSINESS WIRE)--Jan. 15, 2025-- Tempus AI, Inc. (NASDAQ: TEM), a technology company leading the adoption of AI to advance precision medicine and patient care, today announced the national launch of the company's FDA-approved, NGS-based in vitro diagnostic device, xT CDx. Beginning today, xT CDx is now available for all ordering clinicians nationwide. xT CDx is a FDA-approved test that delivers comprehensive insights with one of the largest reported gene panels available.

xT CDx is a 648-gene next-generation sequencing test for solid tumor profiling, which includes microsatellite instability status and companion diagnostic claims for colorectal cancer patients. xT CDx leverages a normal-matched approach, which is a method of parallel DNA sequencing of a solid tumor and normal patient sample that can lead to more accurate identification of cancer-driving somatic variants. All orders for tumor + normal match tests – traditionally run on the company's signature xT assay – will now be run as xT CDx with no changes to the current ordering workflow.

"We are thrilled to broadly introduce our xT CDx test, which combines the trusted performance our clinicians rely on, now with FDA approval," said Ezra Cohen, MD, Chief Medical Officer of Oncology at Tempus. "Tempus has an unwavering commitment to providing high quality and robust assays so clinicians have the most comprehensive and actionable insights in a timely manner. This is consistent with the goal of improving the outcomes for all of their patients, and we look forward to providing xT CDx nationally to make that possible."

Clinicians can enhance molecular insights by adding xR RNA sequencing, xF/xF+ liquid biopsy, immunohistochemistry tests such as HER2 and PD-L1, and algorithmic tests such as homologous recombination deficiency (HRD) and immune profile score (IPS), which promote a streamlined, one-stop experience, supporting patient care. For more information about Tempus' xT CDx, visit tempus.com.

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 and important risk information, please visit tempus.com/resources/content/document-library.

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.

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 potential impact of xT CDx and other tests and the timing of the availability of such testing. 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 September 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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