CMS Awards Tempus With Advanced Diagnostic Laboratory Test (ADLT) Status for its xT CDx Test

July 2, 2024

CHICAGO--(BUSINESS WIRE)--Jul. 2, 2024-- Tempus AI, Inc. (NASDAQ: TEM), a leader in artificial intelligence and precision medicine, today announced that the Centers for Medicare & Medicaid Services (CMS) has granted Advanced Diagnostic Laboratory Test (ADLT) status for Tempus' next-generation sequencing assay, xT CDx. xT CDx is the first Food and Drug Administration (FDA)-approved next-generation sequencing assay to perform matched normal sequence analysis to provide tumor mutation profiling for patients with solid organ neoplasms.

This CMS determination affirms that Tempus' xT CDx meets the rigorous criteria for new ADLT status, which is reserved for novel products that provide new clinical diagnostic information that cannot be obtained any other way, or products cleared or approved by the FDA. The initial ADLT rate established by CMS is $4,500. During the nine-month period beginning July 1, 2024 and ending March 31, 2025, Tempus shall be reimbursed the established ADLT rate while it collects and submits to CMS the private payor payment amounts for xT CDx. Beginning April 1, 2025, CMS will establish a new Medicare rate based on the weighted median of private payer amounts.

"Since our inception, we have remained committed to expanding access to precision medicine solutions to all patients, and this designation is a significant milestone in our commitment to improving patient care through high-quality clinical laboratory testing," said Ezra Cohen, MD, Chief Medical Officer of Oncology at Tempus. "We are grateful that CMS recognizes Tempus' novel, high-quality approach to delivering physicians the molecular data necessary to improve patient outcomes."

Please visit CMS.gov for more information about ADLTs, and for more information about Tempus' xT CDx, visit tempus.com.

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 test reimbursement for covered services, the intended uses of xT CDx and the potential for the xT CDx assay to improve patient outcomes. 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: changing Medicare rates; the intended use of Tempus' products and services; 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' Final Prospectus filed with the Securities and Exchange Commission ("SEC") on June 17, 2024, pursuant to Rule 424(b)(4) under the Securities Act, 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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