Tempus Receives FDA Approval for Tumor Only xT CDx, Enabling Migration of its Entire DNA Solid Tumor Portfolio

May 29, 2026

CHICAGO--(BUSINESS WIRE)--May 29, 2026-- Tempus AI, Inc. (NASDAQ: TEM), a technology company leading the adoption of AI to advance precision medicine, today announced that the U.S. Food and Drug Administration (FDA) has granted approval for a tumor-only indication for its xT CDx next-generation sequencing platform. With this expanded label, Tempus is the first laboratory to hold FDA companion diagnostic (CDx) approval for both tumor-only and tumor-normal comprehensive genomic profiling.

Tempus xT CDx is a 648-gene tissue-based assay intended for molecular profiling of all solid tumor malignancies. It also serves as a companion diagnostic to identify colorectal cancer patients who may benefit from targeted therapies, specifically Erbitux® (cetuximab) and Vectibix® (panitumumab).

While xT CDx previously required a patient's matched normal sample, this regulatory milestone allows the test to run as a tumor-only assay when a matched normal specimen (blood or saliva) is not viable or available. This approval paves the way for Tempus to migrate its entire DNA solid tumor portfolio to FDA-approved assays priced under its current ADLT (Advanced Diagnostic Laboratory Test) pricing.

"This approval marks a milestone in both our regulatory and reimbursement strategy, as this allows the migration of our entire solid tumor DNA portfolio to be under unified ADLT pricing," said Jim Rogers, Chief Financial Officer at Tempus. "As we have previously highlighted, we expect an estimated $200 ASP benefit beginning in 2027 as a result of this approval."

"Our goal is to support clinicians with advanced genomic profiling options," said Kate Sasser, PhD, Chief Scientific Officer at Tempus. "With FDA approval for both tumor-only and tumor-normal comprehensive genomic profiling, Tempus xT CDx provides flexibility for a range of clinical scenarios. While tumor-normal matched sequencing remains an important approach, we recognize that a matched sample is not always available, and now, patients can still benefit from an FDA-approved test that can help inform treatment decisions."

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 in patients with previously diagnosed solid malignant neoplasms. The assay uses DNA isolated from Formalin-Fixed Paraffin Embedded (FFPE) tumor tissue specimens and, when available, patient-matched blood or saliva specimens. Additionally, the device detects microsatellite instability (MSI) status based on a genomic signature from the tumor specimen only. 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.

Click to view the complete xT CDx label, including companion diagnostic indications and important risk information.

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, the timing of the availability of such testing, and the potential financial impact of migrating our solid tumor portfolio to FDA approved assays. 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: 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' Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission ("SEC") on February 24, 2026, 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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