Tempus Announces a Collaboration with Verastem to Develop CDx for First-Ever FDA-Approved KRAS-Mutant Recurrent Low-Grade Serous Ovarian Cancer Combination Treatment

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CHICAGO--(BUSINESS WIRE)--May 20, 2025-- Tempus AI, Inc. (NASDAQ: TEM), a technology company leading the adoption of AI to advance precision medicine and patient care, today announced a collaboration to develop a companion diagnostic (CDx) test with Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with RAS/MAPK pathway-driven cancers. Tempus completed confirmatory testing in Verastem's Phase 2 RAMP-201 clinical trial, which evaluated the combination of avutometinib and defactinib to treat recurrent low-grade serous ovarian cancer (LGSOC) and was the basis of the recent U.S. Food and Drug Administration's (FDA) accelerated approval of the combination in KRAS-mutated recurrent LGSOC.

LGSOC is a rare form of ovarian cancer that disproportionately affects younger women, is highly recurrent and has a poor response rate to chemotherapy. It accounts for approximately 6% to 10% of serous ovarian cancers[1]. Tempus' FDA-approved xT CDx assay is being leveraged as an investigational assay in Verastem's global Phase 3 RAMP-301 clinical trial. The investigational assay prospectively assesses KRAS status in patients with recurrent LGSOC to group patients into KRAS-mutation or KRAS-wild type cohorts for analysis in the primary and secondary endpoints of the study.

"We look forward to continuing to work with Verastem to pursue an unmet need for patients with LGSOC, who, until now, had very few treatment options," said Mike Yasiejko, Executive Vice President and General Manager, Genomics, at Tempus. "Our xT CDx assay is uniquely positioned to support this work."

"Collaborating with Tempus to evaluate KRAS mutation status using the xT assay was an important component of the RAMP-201 clinical trial. Continuing our collaboration to fully develop a CDx assay is part of our post-marketing commitment to the FDA for our recent accelerated approval of avutometinib plus defactinib and is a critical step in bringing targeted therapies to patients with recurrent KRAS-mutant LGSOC," said John Hayslip, MD, Chief Medical Officer of Verastem Oncology.

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 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' document library here.

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 the expected outcomes and benefits of the collaboration with Verastem Oncology. 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 fiscal quarter ended February 24, 2025 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.

[1] Wang Q, Cao SH, Li YY, Zhang JB, Yang XH, Zhang B. Advances in precision therapy of low-grade serous ovarian cancer: A review. Medicine (Baltimore). 2024;103(17):e34306. doi:10.1097/MD.0000000000034306

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