Tempest Announces Interim Results from Ongoing REDEEM-1 Trial of TPST-2003, Preparing for Potential U.S. Registrational Study in 2026

February 25, 2026

- *100% complete response (CR) rate among all six efficacy evaluable patients*
- *Favorable safety profile with no Grade ≥3 CRS or ICANS*
- *Prior investigator-initiated trial (IIT) reached median progression free survival (PFS) of 23.1 months, including in patients with extramedullary disease*
- *36 patients with relapsed/refractory multiple myeloma treated to date across two studies*
- *Tempest plans to submit a U.S. IND and, subject to clearance, initiate a U.S. registrational study in 2026*

BRISBANE, Calif., Feb. 25, 2026 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST) ("Tempest"), a clinical-stage biotechnology company developing a pipeline of advanced cell therapy and small molecule product candidates to treat cancer, today announced clinical data from the ongoing REDEEM-1 Phase 1/2a trial evaluating TPST-2003, a CD19/BCMA dual-targeting CAR-T therapy.

TPST-2003 is an autologous CD19/BCMA dual-targeting CAR-T therapy designed to improve response depth and durability in patients with relapsed/refractory multiple myeloma ("rrMM") through a parallel dual-targeting CAR structure designed to address tumor heterogeneity and antigen escape. TPST-2003 is being developed in China by Tempest's partner, Novatim Immune Therapeutics ("Novatim"). Under its agreement with Novatim, Tempest has the exclusive right to develop TPST-2003 outside of China, India, Turkey, and Russia.

As of the January 31, 2026 data cutoff, a total of 36 patients with rrMM had received one infusion of TPST-2003, including 24 patients in a prior Phase 1/2 IIT and 12 patients in the ongoing REDEEM-1 trial, representing one of the largest datasets evaluating a CD19/BCMA dual-targeting CAR-T therapy. As of the data cutoff, patients enrolled in the REDEEM-1 trial have received a median of four prior lines of therapy.

All six patients currently evaluable for efficacy in the REDEEM-1 trial – three treated at dose level 1 (1×10^6 cells/kg) and three at dose level 2 (2×10^6 cells/kg) – achieved a CR according to the International Myeloma Working Group (IMWG) uniform response criteria. Among 25 evaluable patients with measurable disease at baseline across both studies, the overall response rate ("ORR") was 100% (25/25).

Clinical responses were observed consistently across dose levels and study settings, which Tempest believes supports the reproducibility of TPST-2003's parallel dual-targeting CAR architecture. Tempest plans to present the results of the REDEEM-1 trial and updated results from the IIT at a scientific meeting later this year.

"These results have the potential to raise the bar for clinical effect in relapsed/refractory multiple myeloma (rrMM)," said Dr. Matt Angel, President and Chief Executive Officer of Tempest. "The data from the ongoing REDEEM-1 trial suggest a favorable safety and efficacy profile that could set TPST-2003 apart from currently approved CAR-T therapies and offer a safe, effective option for patients with rrMM. We believe that replicating these results in the remainder of the REDEEM-1 trial and also in a registrational trial would position TPST-2003 as a class-leading therapy for rrMM, and we have therefore made the decision to accelerate our development of TPST-2003. Given the favorable safety profile and demonstrated clinical effect, Tempest is also exploring potential development of TPST-2003 to include patients with large B-cell lymphoma (LBCL) and other related indications."

Favorable Safety Profile Observed Across All Dose Levels in REDEEM-1

As of the January 15, 2026 data cutoff, TPST-2003 demonstrated a favorable safety profile across all dose levels evaluated in REDEEM-1. As of the data cutoff, patients in the REDEEM-1 trial experienced:

- No Grade three or higher cytokine release syndrome (CRS)
- One patient treated at the highest dose level (3×10^6 cells/kg) experienced low-grade immune effector cell-associated neurotoxicity syndrome ("ICANS")
- No Grade three or higher ICANS

The observed safety profile together with the consistency of responses observed in the REDEEM-1 trial support Tempest's plan to accelerate its development timeline and meet with the FDA to discuss initiating a U.S. registrational study later this year.

Deep Responses and Durable Disease Control

Tempest believes the results of the ongoing REDEEM-1 study are consistent with prior clinical results, including a 24-patient Phase 1/2 IIT. In the IIT, among 19 evaluable patients with measurable disease at baseline:

- ORR was 100% (19/19)
- CR rate was 89.5% (17/19)
- At the highest dose level, CR was observed in 100% of patients (5/5)

The IIT also demonstrated durable disease control, with:

- Median progression-free survival (PFS) of 23.1 months across all patients
- Median PFS of 23.1 months in patients with extramedullary disease (EMD)
- All evaluable patients remained MRD-negative at month 12 (5/5)

Patients with EMD are often associated with worse outcomes and shorter disease control in rrMM. Tempest believes these findings support continued evaluation of TPST-2003 for its potential to deliver both deep and durable responses in advanced disease.

Parallel Dual-Targeting CAR Structure Designed to Address Resistance Mechanisms

TPST-2003 incorporates a proprietary parallel dual-targeting CAR architecture designed by Tempest's partner, Novatim Immune Therapeutics.

"The differentiated parallel structure of TPST-2003's dual-targeting CAR is designed to address the challenges of relapse and suboptimal efficacy of other approaches," said Guoxiang Wu, M.D., Chairman and General Manager of Novatim. "TPST-2003 has shown compelling efficacy results in rrMM and POEMS syndrome. In particular, we believe the favorable safety profile of TPST-2003 supports its potential in additional indications including autoimmune diseases and may provide broader clinical benefits for patients worldwide."

Positioning within the Treatment Landscape

Approved CAR-T therapies have demonstrated meaningful clinical benefit in patients with rrMM and represent an important treatment option in later lines of therapy. However, relapse remains common, and treatment can be associated with toxicity management challenges and manufacturing constraints.

TPST-2003 was designed with a parallel dual-targeting CAR structure intended to address tumor heterogeneity and antigen escape, mechanisms believed to contribute to disease progression following currently available therapies.

In addition, Tempest's parallel CAR architecture is being applied across multiple programs, including:

- TPST-3003, an allogeneic CD19/BCMA dual-targeting CAR-T therapy under development for rrMM
- TPST-4003, an in vivo CD19/BCMA dual-targeting CAR-T therapy under development for systemic lupus erythematosus (SLE) and other immunology disorders

Tempest expects initial clinical data from both programs later this year and believes this platform approach may allow these therapies to ultimately benefit a larger number of patients.

Next Steps

Tempest plans to present the complete results from the ongoing Phase 1/2a REDEEM-1 study, as well as updated data from the Phase 1/2 IIT, in 2026. Based on data generated to date, Tempest intends to submit a U.S. IND application and, subject to clearance, initiate a U.S. registrational study of TPST-2003 in 2026.

About REDEEM-1

REDEEM-1 (Study nos. CTR20233309/NCT06223646) is a Phase 1/2a clinical trial evaluating TPST-2003 in patients with relapsed/refractory multiple myeloma, including patients with high-risk cytogenetics and patients with extramedullary disease. The REDEEM-1 trial has a targeted full enrollment of 29 patients. The REDEEM-1 trial is sponsored and being conducted by Tempest's partner, Novatim Immune Therapeutics, with a total of eight clinical sites registered in China: Peking Union Medical College Hospital (Dr. Jian Li; lead site), The First Affiliated Hospital of Nanchang University (Dr. Fei Li), Peking University First Hospital (Dr. Yujin Dong), Henan Cancer Hospital (Dr. Baijun Fang), Shanxi Provincial Cancer Hospital (Dr. Liping Su), The Second Xiangya Hospital of Central South University (Dr. Hongling Peng), The First Affiliated Hospital of China Medical University (Dr. Xiaojing Yan), and The Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College (Dr. Dehui Zou).

Additional clinical trials evaluating TPST-2003

A Phase 1/2 IIT (Study no. NCT04714827) is evaluating TPST-2003 in patients with relapsed/refractory multiple myeloma, including patients with high-risk cytogenetics and patients with extramedullary disease. The IIT is sponsored and being conducted by Tempest's partner, Novatim Immune Therapeutics, with a total of two clinical sites registered in China: Shanghai Fourth People's Hospital (Dr. Weijun Fu; lead site) and Shanxi Provincial Cancer Hospital (Dr. Liping Su).

A Phase 1 trial (Study nos. CTR20242409/NCT06518876) is evaluating TPST-2003 in patients with POEMS, a rare blood disorder caused by abnormal plasma cells. The Phase 1 trial is sponsored and being conducted by Tempest's partner, Novatim Immune Therapeutics, with a total of three clinical sites registered in China: Peking Union Medical College Hospital (Dr. Jian Li; lead site), Xuanwu Hospital Capital Medical University (Dr.

Wanling Sun), and West China Hospital, Sichuan University (Dr. Yu Wu).

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage biotechnology company developing a pipeline of advanced cell therapy and small molecule product candidates to treat cancer. Tempest is headquartered in Brisbane, California. More information about Tempest can be found on the company's website at https://www.tempesttx.com.

Forward-Looking Statements

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the "Securities Act")) concerning Tempest Therapeutics, Inc. These statements may discuss goals, intentions, and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Tempest Therapeutics, as well as assumptions made by, and information currently available to, management of Tempest Therapeutics. Forward-looking statements contained in this press release include but are not limited to statements relating to: Tempest Therapeutics' plan to present data from clinical trials, including the REDEEM-1 trial; the design, initiation, progress, timing, scope and results of clinical trials, including the anticipated initiation of U.S. registrational trial for TPST-2003 in 2026; Tempest Therapeutics' plans to explore the development of TPST-2003 to include patients with large B-cell lymphoma and other related indications; the planned advancement of a diversified next-generation CAR-T pipeline; anticipated therapeutic benefit and regulatory development of Tempest Therapeutics' product candidates, including TPST-2003; and Tempest Therapeutics' ability to achieve its operational plans. Any forward-looking statements in this press release are based on Tempest Therapeutics' current expectations, estimates and projections about its industry as well as management's current beliefs and expectations of future events only as of today and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to Tempest Therapeutics' need for additional capital to fund its planned programs and operations and to continue to operate as a going concern; unexpected safety or efficacy data observed during preclinical or clinical trials; the possibility that results from prior clinical trials and preclinical studies may not necessarily be predictive of future results; past results may not be indicative of future results; clinical trial site activation or enrollment rates that are lower than expected; loss of key personnel; changes in expected or existing competition; changes in the regulatory environment; risks relating to volatility and uncertainty in the capital markets for biotechnology companies; and unexpected litigation or other disputes. These and other factors that may cause actual results to differ from those expressed or implied are discussed in greater detail in the "Risk Factors" section of Tempest's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, filed with the Securities and Exchange Commission ("SEC") on November 5, 2025, and the "Risk Factors" section under Proposal 5 contained in Tempest's definitive proxy statement on Schedule 14A, filed with the SEC on December 31, 2025, and in other documents filed by Tempest from time to time with the SEC. Except as required by applicable law, Tempest Therapeutics undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Tempest Therapeutics' views as of any date subsequent to the date of this press release and should not be relied upon as prediction of future events. In light of the foregoing, investors are urged not to rely on any forward-looking statement in reaching any conclusion or making any investment decision about any securities of Tempest Therapeutics.

Investor Contacts:

Sylvia Wheeler
Wheelhouse Life Science Advisors
swheeler@wheelhouselsa.com

Aljanae Reynolds
Wheelhouse Life Science Advisors
areynolds@wheelhouselsa.com