Tempest Presents Clinical Update at ISCT 2026 Annual Meeting

May 6, 2026

- *100% complete response ("CR") rate among all 15 CAR-T-naïve efficacy evaluable patients treated with TPST-2003 dual-targeting CD19/BCMA CAR-T across two ongoing Phase 1 trials (REDEEM-1 and POEMS-1)*
- *Favorable safety profile with no Grade ≥3 CRS or ICANS in REDEEM-1 trial evaluating TPST-2003 in relapsed/refractory multiple myeloma ("rrMM")*
- *100% CR as measured by normalization of serum vascular endothelial growth factor levels ("CR $_{VEGF}$") rate among all five efficacy evaluable patients in POEMS-1 trial evaluating TPST-2003 in the rare disease, POEMS syndrome*
- *44 patients treated to date across three studies*
- *Results support clinical benefit of parallel-structure dual-targeting CAR architecture in patients with rrMM, including in patients with extramedullary disease ("EMD")*
- *Median progression free survival of 23.1 months, including in patients with EMD, if replicated in registrational trial, would position TPST-2003 as potentially class-leading therapy for rrMM*

BRISBANE, Calif., May 06, 2026 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST) ("Tempest") today presents its most recent clinical data from its lead dual-targeting chimeric antigen receptor T-cell ("CAR-T") therapy product candidate, TPST-2003, at the International Society for Cell & Gene Therapy ("ISCT") Scientific Annual Meeting in Dublin, Ireland. Updates include the latest data from the ongoing REDEEM-1 Phase 1/2a trial evaluating TPST-2003, as well as progress in Tempest's other dual-targeting CAR-T pipeline programs.

Earlier this year, Tempest announced positive interim data from REDEEM-1, including a 100% complete response ("CR") rate among all six efficacy then-evaluable patients according to the International Myeloma Working Group ("IMWG") uniform response criteria, as well as a favorable safety profile. Today's clinical update more than doubles the previous dataset, achieving a 100% CR rate among all 15 CAR-T-naïve efficacy evaluable patients across two ongoing Phase 1 trials – REDEEM-1 evaluating TPST-2003 in relapsed/refractory multiple myeloma ("rrMM") (10/10 according to the IMWG uniform response criteria) and POEMS-1 evaluating TPST-2003 in POEMS syndrome (5/5 CR_{VEGF}).

To date, a total of 44 patients have received one infusion of TPST-2003, including 24 patients in a prior Phase 1/2 investigator-initiated trial ("IIT") evaluating TPST-2003 in rrMM, 13 patients in the ongoing REDEEM-1 trial, and seven patients in the ongoing POEMS-1 trial, representing one of the largest datasets evaluating a CD19/BCMA dual-targeting CAR-T therapy.

All 10 CAR-T-naïve patients currently evaluable for efficacy in the REDEEM-1 trial – three treated at dose level 1 (1×10^6 cells/kg), three at dose level 2 (2×10^6 cells/kg), and four at dose level 3 (3×10^6 cells/kg) – achieved a CR according to the IMWG uniform response criteria. A single patient, who had previously received a BCMA-targeting CAR-T, did not respond. Among 29 CAR-T-naïve evaluable patients with measurable disease at baseline across REDEEM-1 and the prior Phase 1/2 IIT, including 18 patients with EMD, the overall response rate ("ORR") was 100% (29/29) according to the IMWG uniform response criteria.

In the POEMS-1 trial, as of the January 31, 2026 data cutoff, all five evaluable patients had achieved a CR_{VEGF} within two months of being administered TPST-2003. No dose-limiting toxicities were observed in any of the treated patients.

"The results that we are presenting at ISCT this week support our belief that TPST-2003 could offer a life-saving option for patients with rrMM, and, if approved, may outperform first-generation single-targeting CAR-T therapies, in particular in patients with EMD" said Dr. Matt Angel, President and Chief Executive Officer of Tempest. "We are excited by the potential to offer patients who have relapsed from multiple prior lines of therapy a treatment that may achieve up to complete remission of their cancer."

The observed safety profile (no Grade ≥3 CRS or ICANS), together with the consistency of responses observed in the REDEEM-1 trial continue to support Tempest's plan to pursue its objective of meeting with the FDA to discuss initiating a U.S. registrational study later this year.

Presentation Details

REDEEM-1, a multicenter open-label Phase 1/2a study of a BCMA/CD19 dual-targeting CAR-T therapy in patients with relapsed/refractory multiple myeloma including those with extramedullary disease. Abstract #1268. Oral Presentation, May 6, 2026 (12:00-13:00 GMT) & Poster Reception, May 7, 2026 (18:00-19:30 GMT), Immunotherapy Session. Presenter: Dr. Matt Angel.

About TPST-2003

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.

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 32 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).

About POEMS-1

POEMS-1 is a Phase 1 clinical trial (Study nos. CTR20242409/NCT06518876) evaluating TPST-2003 in patients with POEMS, a rare blood disorder caused by abnormal plasma cells. The POEMS-1 trial has a targeted full enrollment of 12 patients. The POEMS-1 trial is sponsored and being conducted by Tempest's partner, Novatim, 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).

Additional Clinical Trial 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, 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).

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage biotechnology company developing a pipeline of advanced CAR-T cell therapy 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, 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 generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "could," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," "goal," "suggest," "target" and other similar expressions. All statements that are not historical facts are forward-looking statements, including but not limited to, statements regarding: Tempest Therapeutics' plan to present data from clinical trials, including the REDEEM-1 trial and the POEMS-1 trial; the design, initiation, progress, timing, scope and results of clinical trials; 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; Tempest Therapeutics' ability to achieve its operational plans, and Tempest's plan to pursue its objective of meeting with the FDA to discuss initiating a U.S. registrational study later this year. All 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 Therapeutics' Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission ("SEC") on March 30, 2026, and in other documents filed by Tempest Therapeutics 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