Tempest Announces Key Manufacturing Milestone for TPST-2003 Dual-Targeting CD19/BCMA CAR-T

April 22, 2026

- *Delivery of TPST-2003 lentiviral vector to Cincinnati Children's Applied Gene and Cell Therapy Center enables manufacturing activities required for pivotal development*
- *Tech transfer on track to support initiation of potentially registrational study in Q4 2026*
- *Key manufacturing milestone follows Tempest's recent announcement of positive interim data from the ongoing REDEEM-1 Phase 1/2a trial of TPST-2003, including 100% complete response in all six efficacy evaluable patients, and accelerated development timeline*

BRISBANE, Calif., April 22, 2026 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST) ("Tempest"), a clinical-stage biotechnology company developing a pipeline of advanced CAR-T cell therapy product candidates to treat cancer, today announced that it has achieved a key milestone in the development of TPST-2003, Tempest's dual-targeting CD19/BCMA CAR-T therapy under development for the treatment of relapsed/refractory multiple myeloma ("rrMM"). Earlier this month, Tempest's manufacturing partner, Cincinnati Children's Applied Gene and Cell Therapy Center ("AGCTC"), took delivery of the TPST-2003 lentiviral vector, a critical component used in the manufacturing of TPST-2003. This milestone supports Tempest's plans to initiate the first potentially registrational study to evaluate a dual-targeting CAR-T therapy in patients with rrMM, including patients who are experiencing extramedullary disease ("EMD"), later this year.

Tempest recently announced that, as of a 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 investigator-initiated trial ("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, all six efficacy evaluable patients enrolled in the REDEEM-1 trial had achieved a complete response according to the International Myeloma Working Group uniform response criteria. Among 25 evaluable patients with measurable disease at baseline across both studies, the overall response rate was 100% (25/25). The IIT also demonstrated durable disease control, with median progression-free survival ("PFS") of 23.1 months across all patients and median PFS of 23.1 months in patients with EMD. Tempest plans to present the results of the REDEEM-1 trial and updated results from the IIT at a scientific meeting later this year.

"We are pleased by the rapid progress we have been making in partnership with AGCTC," said Dr. Matt Angel, President and Chief Executive Officer of Tempest. "The delivery of lentiviral vector, which is a critical component in the manufacturing of autologous CAR-T products, has enabled us to proceed with the manufacturing activities required for the pivotal development of TPST-2003. We are grateful for our partnership with AGCTC, and we are looking forward to continued rapid progress toward the initiation of a potentially registrational study for TPST-2003 later this year."

AGCTC is a research, development, and manufacturing hub advancing future cell and gene therapy (CGT) treatments for patients with unmet needs. Established in 2001, the center has evolved into a nationally recognized leader in CTG CDMO services with a proven track record that reflects Cincinnati Children's commitment to solving unmet medical needs through translational science. AGCTC is part of the Cincinnati Children's Cancer and Blood Diseases Institute, which is ranked #1 in the nation by U.S. News & World Report for pediatric cancer care.

"We are excited to have achieved this important milestone in the development of TPST-2003," said Dr. Chaozhong Zou, Executive Director and General Manager of AGCTC, Cancer and Blood Diseases Institute, Cincinnati Children's Hospital Medical Center. "The clinical data generated so far support the idea that the parallel-structure dual-targeting CAR architecture of TPST-2003 could offer patients with rrMM a meaningful new treatment option, and we are grateful to be in position to support the development of TPST-2003 by leveraging our extensive experience making novel CAR-T programs IND-ready. We look forward to generating the information needed to support the pivotal development of TPST-2003."

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 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, 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, 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 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; the design, initiation, progress, timing, scope and results of clinical trials, including the anticipated initiation of U.S. registrational trial for TPST-2003 in Q4 2026; 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. 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.

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