

Tempest Reports New Preclinical Data for TPST-1120 in RCC at the AACR Annual Meeting

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BRISBANE, Calif., April 09, 2024 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage biotechnology company developing first-in-classⁱ targeted and immune-mediated therapeutics to fight cancer, today announced that collaborators at the Beth Israel Deaconess Medical Center (BIDMC) at Havard Medical presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting demonstrating that TPST-1120 reduces kidney cancer (RCC) growth as a monotherapy, while also showing increased inhibition when combined with frontline chemotherapy and immunotherapy. These new data further support the clinical benefit observed in the TPST-1120 Phase 1 data presented in an oral presentation at ASCO 2022.

"Preclinical data presented at AACR further demonstrate that TPST-1120 has the potential to positively transform the tumor microenvironment and expand the activity of anti-tumor immunity in kidney cancer," said Sam Whiting, M.D., Ph.D., chief medical officer and head of R&D at Tempest. "The expanding positive preclinical and clinical findings of TPST-1120 reinforce our excitement for this program and support the next phase of clinical development into a pivotal HCC study and the potential to expand into RCC and multiple other cancer types."

Preclinical data presented at AACR showed that TPST-1120 increases infiltrating cytotoxic CD8+ T cells in the tumor microenvironment, consistent with modulation of the tumor microenvironment to a more immune responsive environment that allows for the influx of tumor specific CD8+ T cells.

In preclinical models of renal cell carcinoma (RCC), treatment with TPST-1120 reduced tumor growth by 52%-56% as monotherapy. Additional improvement in anti-cancer activity was demonstrated in combination treatment with standard first-line RCC cabozantinib or anti-PD1 therapy, where tumor inhibition was 81% and 74%, respectively.

These data reinforce previously reported Phase 1 clinical data where objective responses were observed in patients with late line, immune refractory RCC treated with TPST-1120 and the immune therapy, nivolumab, and complement the positive Phase 1b/2 data reported in October 2023 from a global randomized study of TPST-1120 in combination with atezolizumab and bevacizumab in first-line patients with advanced HCC, which showed clinical superiority of the TPST-1120 arm over the control arm across multiple study endpoints and relevant biomarker-defined patient subpopulations.

About TPST-1120

TPST-1120 is an oral, small molecule, selective PPARα antagonist. Tempest's data suggest that TPST-1120 treats cancer by targeting tumor cells directly and by modulating immune suppressive cells and angiogenesis in the tumor microenvironment. In an ongoing global randomized phase 1b/2 study of TPST-1120 in combination with atezolizumab and bevacizumab in first-line patients with advanced HCC, the TPST-1120 arm showed clinical superiority across multiple study endpoints when compared to atezolizumab and bevacizumab alone, the standard of care. These randomized data were supported by positive results observed in the Phase 1 clinical trial in patients with heavily pretreated advanced solid tumors. TPST-1120 is wholly-owned by Tempest.

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage biotechnology company advancing a diverse portfolio of small molecule product candidates containing tumortargeted and/or immune-mediated mechanisms with the potential to treat a wide range of tumors. The company's novel programs range from early research to later-stage investigation in a randomized global study in first-line cancer patients. Tempest is headquartered in Brisbane, California. More information about Tempest can be found on the company's website at 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 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," and other similar expressions. All statements that are not historical facts are forward-looking statements, including any statements regarding: the design, initiation, progress, timing, scope and results of clinical trials; anticipated therapeutic benefit and regulatory development of the Company's product candidates; the Company's ability to deliver on potential value-creating milestones; the Company's ability to advance into a late-stage clinical company; and the Company's ability to achieve its operational plans. Forward-looking statements are based on information available to Tempest Therapeutics as of the date hereof and are not guarantees of future performance. Any factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical trials; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied are discussed in greater detail in the Form 10-K filed by Tempest Therapeutics with the Securities and Exchange Commission on March 19, 2024 and other documents filed by the Company from time to time with the Securities and Exchange Commission. 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 a 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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i If approved by the FDA