FDA Study May Proceed Notice Received for Phase 2 Trial of TPST-1495 for the Treatment of Familial Adenomatous Polyposis (FAP)

March 13, 2025

Second clinical program entering Phase 2 with data expected 2026

BRISBANE, Calif., March 13, 2025 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage biotechnology company developing first-in-class[1] targeted and immune-mediated therapeutics to fight cancer, today announced that the Cancer Prevention Clinical Trials Network received a “Study May Proceed” letter from the U.S. Food and Drug Administration (FDA) to evaluate TPST-1495, the company’s novel dual receptor inhibitor of prostaglandin (PGE2) signaling, in a Phase 2 clinical trial for the treatment of patients with Familial Adenomatous Polyposis (FAP).

“Receiving the FDA’s clearance to proceed with our Phase 2 clinical trial for TPST-1495, our second clinical program, in FAP marks an important step forward in developing new treatment options for patients suffering from this high-risk disease that significantly increases the risk of multiple GI cancers,” said Sam Whiting M.D., Ph.D., chief medical officer and head of R&D of Tempest. “This collaboration with the Cancer Prevention Clinical Trials Network, financially supported by the National Cancer Institute’s Division of Cancer Prevention, underscores the urgent need for innovative approaches in cancer prevention, and we look forward to advancing this potential promising therapy to help patients facing this difficult disease."

The Phase 2 study in patients with FAP will begin this year and will be run by the Cancer Prevention Clinical Trials Network and funded by the National Cancer Institute (“NCI”) Division of Cancer Prevention.

About the TPST-1495 FAP Study

The planned Phase 2 study will evaluate the efficacy and safety of TPST-1495 in patients with Familial Adenomatous Polyposis (FAP) who have previously undergone colectomy. The primary efficacy objective is to assess the activity of TPST-1495 in reducing duodenal polyp burden in patients with FAP comparing baseline endoscopy to endoscopy after 6 months of treatment with TPST-1495. Additional objectives include reduction of polyp burden in retained rectum or IPAA and to assess the safety of TPST-1495.

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage biotechnology company advancing a diverse portfolio of small molecule product candidates containing tumor-targeted 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, including the anticipated Phase 3 study for amezalpat; anticipated therapeutic benefit and regulatory development of the Company’s product candidates 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 “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q filed for the quarter ended September 30, 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 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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[1] If approved by the FDA