Tempest Receives FDA Study May Proceed for Pivotal Phase 3 Trial of Amezalpat Combination Therapy for the Treatment of First-Line Hepatocellular Carcinoma

November 12, 2024

BRISBANE, Calif., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage biotechnology company developing first-in-class[i] targeted and immune-mediated therapeutics to fight cancer, today announced that the company received a "Study May Proceed" letter from the U.S. Food and Drug Administration (FDA) to evaluate amezalpat (TPST-1120) in combination with atezolizumab and bevacizumab, the current standard of care, versus the standard of care alone in a pivotal randomized Phase 3 trial for the first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC).

"The clinical and regulatory team at Tempest are thrilled to receive this notice from FDA with respect to the planned pivotal Phase 3 trial to evaluate amezalpat as a potential treatment for first-line liver cancer," said Sam Whiting M.D., Ph.D., chief medical officer and head of R&D of Tempest. "Previously reported positive Phase 2 data underscore amezalpat's potential to improve the survival of patients facing this life-threatening disease, and our team is dedicated to advancing the program and bringing amezalpat to patients."

About the TPST-1120-301 Study (NCT06680258)

The planned Phase 3 study is a global, blinded, 1:1 randomized study of amezalpat plus atezolizumab and bevacizumab versus placebo plus atezolizumab and bevacizumab, the standard of care, for the first-line treatment of patients with unresectable or metastatic HCC. In August 2024, the company received agreement from the FDA on its Phase 3 study design, dose of amezalpat, and the statistical plan, including a pre-specified efficacy analysis that could shorten the time to primary analysis. The company is working to enable a Phase 3 study to start in the first quarter of 2025.

About Amezalpat

Amezalpat is an oral, small molecule, selective PPARα antagonist. Data suggest that amezalpat 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 amezalpat in combination with atezolizumab and bevacizumab in first-line patients with advanced HCC, the amezalpat arm showed clinical superiority across multiple study endpoints, including overall survival in both the entire population and key subpopulations, when compared to atezolizumab and bevacizumab alone, the standard of care. These randomized data were supported by additional positive results observed in the Phase 1 clinical trial in patients with heavily pretreated advanced solid tumors, including renal cell carcinoma and cholangiocarcinoma.

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 on August 8, 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.

Investor Contacts:

Sylvia Wheeler
Wheelhouse Life Science Advisors

swheeler@wheelhouselsa.com

Aljanae Reynolds
Wheelhouse Life Science Advisors
areynolds@wheelhouselsa.com

[i] If approved by the FDA