Tempest Announces Successful End-of-Phase 2 Meeting with FDA for Amezalpat (TPST-1120) to Treat First-Line Hepatocellular Carcinoma

August 15, 2024

- Broad agreement on pivotal Phase 3 study plan, including use of current amezalpat dose and schedule
- Overall survival, the strongest result from the Phase 2 trial, will be the primary study endpoint
- Agreed-upon early efficacy analysis could reduce time to primary read-out significantly

BRISBANE, Calif., Aug. 15, 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 positive feedback from its end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) for amezalpat (TPST-1120) in combination with atezolizumab and bevacizumab to treat first-line unresectable or metastatic hepatocellular carcinoma (HCC).

"We are thrilled with the positive outcome of our end-of-Phase 2 meeting with the FDA," said Sam Whiting, M.D., Ph.D., chief medical officer and head of R&D at Tempest. "Tempest and the FDA are in broad agreement on all major aspects of the proposed pivotal Phase 3 clinical trial for amezalpat in patients with hepatocellular carcinoma in the first line setting. This planned Phase 3 study closely mirrors the randomized Phase 2 study and the strongly favorable hazard ratio for overall survival observed at top-line analysis of the Phase 2, confirmed at the latest survival follow-up, give us confidence in the potential success of the Phase 3."

Key outcomes of the FDA meeting include:

- Agreement on Phase 3 study design, including the standard-of-care control arm and the primary and secondary study endpoints
- Agreement on appropriateness of the current amezalpat dose and schedule for the Phase 3 study
- Agreement on the Phase 3 statistical plan including a pre-specified early efficacy analysis that the company currently estimates could shorten the time to primary analysis by up to 8 months

About the TPST-1120-301 Study

The planned Phase 3 study is a global, blinded, 1:1 randomized study of amezalpat plus atezolizumab and bevacizumab vs. atezolizumab and bevacizumab, the standard of care, in patients with unresectable or metastatic HCC treated in the first line setting. The company is preparing for the Phase 3 study start in the first quarter of 2025.

About Amezalpat (TPST-1120)

Amezalpat is an oral, small molecule, selective PPARα antagonist. Tempest's 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 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.

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 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 “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 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.

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[i] If approved by the FDA