Tempest Presents New Amezalpat MOA Data Reinforcing Its Potential as Novel Cancer Treatment at the 2025 AACR Annual Meeting

April 28, 2025

BRISBANE, Calif., April 28, 2025 (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 a presentation of new data supporting the immune component of amezalpat's purported dual mechanism of action that reinforces its potential as a novel cancer treatment at the 2025 American Association for Cancer Research (AACR) Annual Meeting.

"The data presented at the AACR Annual Meeting show that amezalpat reduced tumor promoting immunosuppression by M2 macrophages and T regulatory cells resulting in immune activation. These data support the immune-mediated anti-cancer activity of the proposed dual MOA of amezalpat," said Sam Whiting, M.D., Ph.D., chief medical officer and head of R&D at Tempest, "and are consistent with clinical data showing promising results in patients with HCC, RCC and CCA including in combination with approved immunotherapy. The results reinforce amezalpat's novel and potentially first-in-class profile as a cancer therapy."

Amezalpat is an inhibitor of PPAR-alpha, the key regulator of fatty acid oxidation (FAO), which is a key metabolic pathway used by immunosuppressive macrophages and regulatory T cells (Tregs). Both cell populations are associated with poor prognosis in multiple cancer indications. Data presented demonstrated that amezalpat inhibits the development of these cells from precursor populations and is associated with reduced mitochondrial mass, the site of FAO, in immunosuppressive macrophages. Additionally, treatment of Tregs or immunosuppressive macrophages with amezalpat in the presence of tumor and cytotoxic T cells decreases anti-inflammatory cytokine production, indicating blockade of immune suppression that likely contributes to the efficacy of amezalpat observed in clinical trials.

About Amezalpat

Amezalpat is an oral, small molecule, selective PPARα antagonist. Data suggests that amezalpat treats cancer by targeting tumor cells directly and by modulating immune suppressive cells and angiogenesis in the tumor microenvironment. In a 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, as that term is defined under the federal securities laws, that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "may," "will," "should," "would," "could", "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions. Forward-looking statements contained in this press release include but are not limited to statements relating to: the initiation, timing and results of the Phase 2 study for TPST-1495; and the ability of TPST-1495 to benefit from the ODD designation, including potential tax credits and market exclusivity. Any 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, risks relating to: changes in the regulatory environment resulting in potentials delays in the clinical development and regulatory approval of our product candidates, including TPST-1495; the volatility and uncertainty in the capital markets for biotechnology companies; and our ability to raise additional capital or other pursue our plan to identify and complete a strategic transaction on attractive terms or at all. 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 the company's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission (SEC) on March 27, 2025, as well as in other filings the company may make with the SEC in the future. 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