Tempest Announces Plan to Explore Strategic Alternatives to Advance Promising Pipeline of Clinical Oncology Assets and Maximize Stockholder Value

April 9, 2025

- *Amezalpat (TPST-1120) is Phase 3-ready: completed FDA and EMA interactions for first-line pivotal study in hepatocellular carcinoma (HCC); global investigator support in place*
- *Awarded both Orphan Drug & Fast Track designations for amezalpat based on positive randomized Phase 2 data in first-line HCC*
- *Received FDA "Study May Proceed" letter for TPST-1495 in a Phase 2 trial for the treatment of familial adenomatous polyposis (FAP); data expected 2026*

BRISBANE, Calif., April 09, 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 the company plans to explore a full range of strategic alternatives to advance its promising clinical stage programs and maximize stockholder value. Strategic alternatives under consideration may include, but are not limited to, mergers, acquisition, partnerships, joint ventures, licensing arrangements or other strategic transactions. The company has retained MTS Health Partners, L.P., an internationally recognized financial advisor with substantial experience in the biotechnology industry, to support it with the strategic evaluation process.

"Notwithstanding the positive randomized data set from the amezalpat Phase 2 and its blockbuster potential in first-line HCC, as well as the potential of TPST-1495 as it moves towards a Phase 2 in FAP, the capital markets have been unavailable to support the next stage of advancement," said Stephen Brady, president and chief executive officer of Tempest. "We are initiating a process to explore alternatives available to the company to maximize stockholder value, which include finding a strategic partner with the resources to develop what we believe are potentially life-saving therapies for patients in need. Given the positive data and commercial potential with this pipeline, as well as the clearance from FDA on the lead program's pivotal study, we believe this is a rare opportunity for a partner."

The company has not set a timetable for completion of the process for evaluating strategic alternatives and does not intend to disclose further developments or guidance on the status of its programs or the process for evaluating strategic alternatives unless and until it is determined that further disclosure is appropriate or necessary. No agreement providing for any transaction has been reached and there can be no assurances that any transaction will result from the process for evaluating strategic alternatives. If the process for evaluating strategic alternatives results in an agreement regarding a transaction, there can be no assurances that any transaction will be completed.

Program Milestones and Status

Amezalpat (TPST-1120) (clinical PPARα antagonist)**:**

- Granted both Orphan Drug and Fast Track designations by the U.S. Food and Drug Administration (FDA) for amezalpat for the treatment of patients with HCC.
- Received a "Study May Proceed" letter from the FDA to evaluate amezalpat in combination with atezolizumab (TECENTRIQ®) and bevacizumab (Avastin®), the current standard of care for unresectable or metastatic HCC, in a pivotal Phase 3 trial for the first-line treatment of unresectable or metastatic HCC.
- Announced an agreement with F. Hoffmann-La Roche Ltd. (Roche) to advance the evaluation of amezalpat in combination with atezolizumab and bevacizumab into a pivotal Phase 3 trial for the first-line treatment of unresectable or metastatic HCC.
- Announced positive feedback from the end-of-Phase 2 meeting with the FDA for amezalpat in combination with atezolizumab and bevacizumab to treat first-line unresectable or metastatic HCC.
- Reported new positive survival data from the ongoing global randomized Phase 1b/2 clinical study demonstrating that amezalpat delivered a six-month improvement in median overall survival (OS) when combined with atezolizumab and bevacizumab in comparison to atezolizumab and bevacizumab alone, the standard of care, in the first-line treatment of patients with unresectable or metastatic HCC.
- Published positive data from the Phase 1 trial of amezalpat in patients with advanced solid tumors in the Journal of Cancer Research Communications. Data showed that amezalpat demonstrated clinical activity, including tumor shrinkage, even in PD-1 inhibitor-refractory and immune-compromised cancers. These data complement the positive Phase 1b/2 data reported in October 2023 and June 2024 from a global randomized study of amezalpat in combination with atezolizumab and bevacizumab in first-line patients with advanced HCC.
- Reported new preclinical data at the 2024 American Association for Cancer Research (AACR) Annual Meeting demonstrating that amezalpat reduced kidney cancer growth as a monotherapy, while also showing increased inhibition

when combined with frontline chemotherapy and immunotherapy.

TPST-1495 (clinical dual EP2/4 prostaglandin receptor antagonist):

- Granted Orphan Drug designation by the FDA for TPST-1495 for the treatment of patients with FAP.
- Received a “Study May Proceed” letter from the FDA to evaluate TPST-1495 in a Phase 2 trial for the treatment of FAP.

About Amezalpat (TPST-1120)

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 TPST-1495

TPST-1495 is a novel, highly selective and potent EP2-EP4 dual antagonist designed to block the cancer-promoting EP2 and EP4 receptors in the prostaglandin (PGE2) pathway, while sparing the homologous but differentially active EP1 and EP3 receptors. PGE2 signaling through EP2 and EP4 has been observed to enhance tumor progression through the stimulation of tumor proliferation, enhanced angiogenesis and suppression of immune function in the tumor microenvironment. The Phase 2 study of TPST-1495 in patients with FAP is expected to begin in 2025 under the auspices of the Cancer Prevention Clinical Trials Network and funded by the National Cancer Institute (NCI) Division of Cancer Prevention.

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. Forward-looking statements contained in this press release include but are not limited to statements relating to Tempest Therapeutics’ evaluation of strategic alternatives available to the company to maximize stockholder value, as well as the design, initiation, progress, timing, scope and results of clinical trials, including the potential Phase 3 study for amezalpat and Phase 2 trial of TPST-1495; and anticipated therapeutic benefit and regulatory development of the Tempest Therapeutics product candidates. 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 volatility and uncertainty in the capital markets for biotechnology companies; availability of suitable third parties with which to conduct contemplated strategic transactions; and whether we will be able to pursue a strategic transaction, or whether any transaction, if pursued, will be completed 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 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