Tempest Announces Agreement with Roche to Support Advancement of Amezalpat Combination Therapy into First-Line Hepatocellular Carcinoma Pivotal Trial

October 10, 2024

The company is preparing for the Phase 3 study start in the first quarter of 2025

BRISBANE, Calif., Oct. 10, 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 an agreement with Roche to advance the evaluation of amezalpat (TPST-1120) in combination with atezolizumab (Tecentriq®) and bevacizumab, the current standard of care for unresectable or metastatic hepatocellular carcinoma (HCC), into a pivotal Phase 3 trial for the first-line treatment of unresectable or metastatic hepatocellular carcinoma, a form of liver cancer with high unmet need.

Under the agreement, Roche will supply atezolizumab globally and Tempest will sponsor and lead the pivotal study. This agreement builds on a clinical collaboration between the companies pursuant to which amezalpat was combined with atezolizumab and bevacizumab in first-line HCC patients and compared to atezolizumab and bevacizumab alone in a randomized Phase 1b/2 study. Tempest retains all development and commercial rights to amezalpat.

“We’re excited to announce this agreement that supports the advancement of amezalpat into a pivotal study and reinforces both Tempest and Roche’s shared commitment to delivering groundbreaking cancer treatments for patients,” said Stephen Brady, president and chief executive officer of Tempest. “Based on the positive Phase 2 data, I believe this combination therapy holds the potential to significantly improve first-line liver cancer treatment, and we look forward to amezalpat moving into this pivotal Phase 3 study.”

In June, Tempest reported updated positive survival data from the ongoing global randomized Phase 1b/2 clinical study, demonstrating a six-month improvement in median overall survival (OS) for patients receiving the combination therapy, in comparison to the control arm of atezolizumab and bevacizumab alone in the first-line treatment of patients with unresectable or metastatic HCC. The survival benefit observed in the amezalpat arm was maintained in key subpopulations, as well. These June data build upon previously released data from the primary analysis showing that the amezalpat combination therapy provided clinical benefit regardless of PD-L1 status and in patients with both immune excluded and immune desert tumors. Patients with a mutation in the beta catenin gene had an increased objective response rate and, in the updated data set, a longer median OS, both supported by amezalpat’s purported mechanism of action.

In August, the company held its end-of-phase 2 meeting with the FDA where it reached broad agreement on the Phase 3 study plan, including the amezalpat dose schedule and primary endpoint of OS, which was a positive result from the Phase 2. The FDA also agreed on the statistical plan, including a pre-specified early efficacy analysis that the company currently estimates could shorten the study’s timeline to primary analysis by 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. 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 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. 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 overall population and key subpopulations, 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, 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.

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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