Tempest Announces First Patient Dosed in Randomized Study Evaluating TPST-1120 in First-Line Regimen for Hepatocellular Carcinoma in Clinical Collaboration with Roche

September 20, 2021

Trial to Evaluate TPST-1120/atezolizumab/bevacizumab triplet compared to atezolizumab/bevacizumab alone

SOUTH SAN FRANCISCO, Calif., Sept. 20, 2021 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage oncology company developing potentially first-in-class therapeutics that combine both targeted and immune-mediated mechanisms, today announced the first patient has been dosed in the global randomized Phase 1b/2 clinical study evaluating TPST-1120, Tempest's small molecule PPAR α antagonist, in combination with the standard-of-care regimen of atezolizumab and bevacizumab in the first-line treatment of patients with advanced or metastatic hepatocellular carcinoma ("HCC"). The trial is being conducted under a clinical collaboration with F. Hoffman La-Roche ("Roche").

"The initiation of this randomized TPST-1120 study in collaboration with Roche marks significant progress in the advancement of the Tempest clinical pipeline," said Sam Whiting, MD, Ph.D., chief medical officer of Tempest. "We continue to be excited about TPST-1120's mechanism of action and are encouraged by its safety profile and early signals of clinical benefit seen in both monotherapy and combination studies. The Tempest team looks forward to further evaluation of TPST-1120 in this randomized combination in the first-line treatment of patients with HCC."

"Atezolizumab plus bevacizumab is the standard-of-care for most patients with HCC, but new combinations are needed to further improve patient outcomes," said Mark Yarchoan, M.D., Assistant Professor of Medicine at Johns Hopkins University School of Medicine and Co-Director of the Liver Cancer Multidisciplinary Clinic. "In preclinical models, TPST-1120's mechanism of action is complementary with the immune mechanism of atezolizumab and the anti-VEGF mechanism of bevacizumab. Additionally, activation of the B-catenin pathway, which is quite common in HCC, has been associated with direct benefit from targeting the metabolic pathway inhibited by TPST-1120. For these reasons, the triplet regimen of the three drugs together is particularly interesting for evaluation in patients with HCC."

The Phase 1b/2 global randomized study will evaluate TPST-1120 in combination with the standard-of-care regimen of atezolizumab and bevacizumab in patients with advanced or metastatic HCC not previously treated with systemic therapy. At least 40 and up to 60 patients will receive the TPST-1120 combination at approximately 25 sites worldwide including the United States, Asia, and Europe, and will be compared to the standard-of-care atezolizumab and bevacizumab regimen with primary objectives of anti-tumor activity and safety. Under the terms of the collaboration agreement, Roche will manage the study operations for this global, multicenter trial. Tempest retains global development and commercialization rights to TPST-1120.

About TPST-1120

TPST-1120 is an oral, small molecule, selective PPARα antagonist. Tempest's preclinical data suggest that TPST-1120 can kill tumor cells directly and target suppressive immune pathways in the tumor microenvironment. Both types of targeted cells can be dependent on fatty acid metabolism, which is regulated by the PPARα transcription factor. In extensive non-clinical studies, TPST-1120 as a monotherapy or in combination with other anti-cancer drugs resulted in significant reductions in tumor growth and stimulation of durable anti-tumor immunity. In an ongoing Phase 1 clinical trial, TPST-1120 has been well-tolerated by patients with advanced cancers as monotherapy and in combination with the PD-1 inhibitor nivolumab, and has demonstrated tumor reduction (including according to RECIST criteria), as well as biomarker modulation.

About Hepatocellular Carcinoma

HCC is an aggressive cancer with limited treatment options and is a major cause of cancer deaths worldwide. Every year, more than 815,000 people worldwide are diagnosed with HCC. In the US, the number of liver cancer cases have more than tripled since 1980 and HCC represents the fastest-rising cause of cancer-related death, while in Europe, liver cancer is also on the rise. HCC develops predominantly in people with cirrhosis due to chronic hepatitis (B or C) or alcohol consumption, and typically presents at an advanced stage. The prognosis for unresectable HCC remains poor, with few systemic therapeutic options and a 1-year survival rate of less than 50% following diagnosis.

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage oncology company advancing small molecules that combine both targeted and immune-mediated mechanisms with the potential to treat a wide range of tumors. The company's two novel clinical programs are TPST-1495 and TPST-1120, antagonists of EP2/EP4 and PPARα, respectively. Both TPST-1495 and TPST-1120 are advancing through Phase 1 studies designed to study both agents as monotherapies and in combination with other approved agents. Tempest is also developing an orally available inhibitor of TREX-1 designed to activate the cGAS/STING pathway selectively. Tempest is headquartered in South San Francisco and supported by notable healthcare investors. 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. ("Tempest"). 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, as well as assumptions made by, and information currently available to, management of Tempest. 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”, “potentially,” and other similar expressions. All statements that are not historical facts are forward-looking statements, including: any statements regarding the progress, scope or timing of the development and evaluation in clinical trials of our product candidates; the benefits that may be derived from any future products or the commercial; or market opportunity with respect to any of our future products. Forward-looking statements are based on information available to Tempest as of the date hereof and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: our inability to successfully or timely develop our product candidates; our inability to realize any benefits from any future products; and our failure to realize any commercial or market benefit from future products, if any. These and other risks are described in greater detail in the Form 10-Q filed by Tempest with the Securities and Exchange Commission on August 12, 2021. Except as required by applicable law, Tempest 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’s 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.

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