Tempest Reports Positive TPST-1120 Clinical Data from Phase 1 Trial in Patients with Advanced Solid Tumors at 2022 ASCO Annual Meeting

May 26, 2022

- RECIST responses observed in IO-refractory patients and in IO-resistant indications
  - 30% ORR in patients treated at the two highest TPST-1120 doses in combination with nivolumab (3/10); 20% ORR in all evaluable combination patients (3/15)
  - 53% DCR in monotherapy patients (10/19)
- Responses observed in patients with heavily pre-treated renal cell carcinoma (ORR 50%, 2/4) and cholangiocarcinoma, including patients with cancer that were previously refractory to anti-PD-1 treatment
- TPST-1120 was well-tolerated both as a monotherapy and in combination with nivolumab
- Randomized global Phase 1b/2 study is ongoing in previously untreated patients with hepatocellular carcinoma
- Investor event and webcast featuring key opinion leaders scheduled for Sunday, June 5, at ASCO

SOUTH SAN FRANCISCO, Calif., May 26, 2022 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage oncology company developing therapies that combine both targeted and immune-mediated mechanisms, today announced positive results from its Phase 1 clinical trial of TPST-1120, a first-in-class[1] PPARα antagonist, as a single agent and in combination with nivolumab in patients with advanced solid tumors. The results will be presented in an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL, by Mark Yarchoan, M.D., associate professor of oncology at Johns Hopkins School of Medicine.

Dr. Yarchoan commented, “The anti-cancer activity observed in these late-stage solid tumor patients is encouraging, particularly in light of their treatment history and the difficult nature of the tumor types. Based on the clinical activity observed with monotherapy, and the responses observed with combination therapy in patients with prior progression on checkpoint inhibitor therapy, a tolerable safety profile and distinct mechanism of action, I see significant potential in multiple tumor types and look forward to the ongoing development of TPST-1120.”

Sam Whiting, chief medical officer of Tempest, added, “We are excited to see these positive TPST-1120 results in Tempest’s first presentation of clinical data, especially given the advanced stage and treatment histories of these patients. We look forward to presenting these data at ASCO and the continued development of TPST-1120 in the ongoing first-line randomized study in patients with hepatocellular carcinoma.”

[1] If approved by the FDA

TPST-1120 Monotherapy Results

In the monotherapy portion of the trial, 19 patients with late-line treatment-refractory solid tumors, including pancreatic, cholangiocarcinoma (CCA), and colorectal cancers, were treated with oral twice-daily TPST-1120. The results showed that 53% (10/19) of patients experienced clinical benefit in the form of disease control, including tumor shrinkage in 21% of the patients. Two patients with late-line CCA, an aggressive tumor type and disease setting usually unresponsive to therapy, including IO therapies, achieved durable stable disease and one of the patients achieved durable tumor shrinkage.

TPST-1120 and Nivolumab Combination Therapy Results

In the combination therapy portion of the trial, 15 patients with heavily-pretreated renal cell carcinoma (RCC), hepatocellular carcinoma (HCC) and CCA were treated with oral twice-daily TPST-1120 and the anti-PD-1 therapy, nivolumab. All of the HCC and RCC patients had received an approved anti-PD-1 therapy in at least one prior line of therapy and discontinued that treatment due to disease progression. Promising objective responses (RECIST v1.1) were observed in two patients with late-line RCC who had previously progressed on anti-PD-1 therapy without an objective response (ORR 50%, n=2/4, in evaluable RCC patients). A third RECIST response was observed in a patient with late-line, heavily pre-treated CCA, a tumor type generally not responsive to anti-PD-1 alone.

Notably, all three responders were treated at the two highest doses of TPST-1120 (ORR 30%, 3/10).

Safety

TPST-1120 was well tolerated as both a monotherapy and in combination with nivolumab. The majority of the treatment-related adverse events were Grade 1 and 2, and included nausea, fatigue and diarrhea. No dose-limiting toxicities were reported during dose escalation.

ASCO Events

Presentations Details

Title: A phase 1 study of TPST-1120 as a single agent and in combination with nivolumab in subjects with advanced solid tumors

Session Typer/Title: Oral Abstract Session, Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
Session Date and Time: Tuesday, June 7, 2022; 9:45 a.m. - 12:45 p.m. CDT

Abstract Number: 3005

Title: A phase 1 study of TPST-1495 as a single agent and in combination with pembrolizumab in subjects with solid tumors

Session Type/Title: Poster Session, Developmental Therapeutics – Immunotherapy
Session Date and Time: Sunday, June 5, 2022; 8:00 a.m. – 11:00 a.m. CDT
Abstract Number: TPST2696

Tempest Investor Event

Tempest will host and webcast an investor event in conjunction with the ASCO Annual meeting on Sunday, June 5, 2022 at 6:30 a.m. CDT. Company management will be joined by key thought leaders:

Mark Yarchoan, M.D.
Associate Professor of Oncology
Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

Susanna V. Ulahannan, M.D., MMEd
Assistant Professor of Medicine
Associate Director, Oklahoma TSET Phase 1 Program
Stephenson Cancer Center at the University of Oklahoma

Jason Luke, M.D.
Associate Professor of Medicine
Director - Immunotherapy and Drug Development Center
UPMC Hillman Cancer Center

Toni K. Choueiri, M.D.
Director, Lank Center for Genitourinary Oncology, Dana Farber Cancer Institute
Jerome and Nancy Kohlberg Chair and Professor of Medicine,
Harvard Medical School

To access the live or archived recording of the investor event, please visit the investor section of the Tempest website at https://ir.tempesttx.com.

About TPST-1120

TPST-1120 is a first-in-class[2] oral selective PPARα antagonist with a dual mechanism designed to target both tumor cells directly and suppressive immune cells in the tumor microenvironment. Both types of targeted cells are dependent on fatty acid metabolism, which is regulated by the PPARα transcription factor. In extensive non-clinical studies, TPST-1120 as a monotherapy and in combination with other anti-cancer drugs resulted in significant reductions in tumor growth and stimulation of durable anti-tumor immunity. In addition to the study being presented at ASCO, in collaboration with F. Hoffmann La Roche, TPST-1120 is also advancing through a randomized, first-line, global, Phase 1b/2 clinical study in combination with the standard-of-care regimen of atezolizumab and bevacizumab in patients with advanced or metastatic hepatocellular carcinoma.

[2] If approved by the FDA

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage oncology company advancing small molecules that combine both tumor-targeted and immune-mediated mechanisms with the potential to treat a wide range of tumors. The company's two novel clinical programs are TPST-1120 and TPST-1495, antagonists of PPARα and EP2/EP4, respectively. Both TPST-1120 and TPST-1495 are advancing through clinical trials 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 selectively the cGAS/STING pathway, an innate immune response pathway important for the development of anti-tumor immunity. Tempest is headquartered in South San Francisco. 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 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 timing and selection of development candidates, dose selection or commencement of, or availability of data from, clinical trials or the benefits that may be derived from any products. Forward-looking statements are based on information available to Tempest Therapeutics 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 current or future products; and our failure to realize any commercial or market benefit from current or future products, if any. These and other risks are described in greater detail in the Form 10-Q filed by Tempest Therapeutics with the Securities and Exchange Commission on May 13, 2022. 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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