Tempest Provides ASCO KOL Feedback on TPST-1120 Clinical Results and Updated Financial Guidance

June 9, 2022

- TPST-1120 demonstrated monotherapy clinical benefit in patients with late-line advanced, poor-prognosis cancers where responses would be unexpected
- RECIST responses observed with TPST-1120 combined with anti-PD1 therapy in patients who previously progressed on anti-PD1/PDL1 therapy
- Potential biomarker for patient responsiveness to TPST-1120 identified and will be further explored
- TPST-1120 demonstrated the ability to reprogram the tumor microenvironment (TME) in a tumor type that is refractory to anti-PD1 with low tumor mutation burden
- TPST-1120 is also in an ongoing randomized global Phase 1b/2 clinical study in combination with the standard-of-care regimen of atezolizumab and bevacizumab in first-line patients with hepatocellular carcinoma
- Cash runway into 2024

SOUTH SAN FRANCISCO, Calif., June 09, 2022 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage oncology company developing therapies that combine both targeted and immune-mediated mechanisms, today summarized key takeaways from the TPST-1120 clinical program provided by Mark Yarchoan, M.D., associate professor of oncology at Johns Hopkins School of Medicine, at its June 5th investor event held in connection with the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. The company also revised its cash guidance. Dr. Yarchoan also presented the TPST-1120 Phase 1 results in an oral presentation at ASCO on Tuesday, June 7.

Dr. Yarchoan reviewed and discussed TPST-1120 results both as a single agent and in combination with nivolumab in a webcast presentation that is available on the Tempest website at https://ir.tempesttx.com. His conclusions include:

- The monotherapy arm consisted of one of the more challenging groups of tumors to treat in a Phase 1 trial, e.g., dominated by patients with late-line pancreatic and cholangiocarcinoma (CCA), where he considered stable disease a “win.”
    - A number of patients in the monotherapy arm had meaningfully-prolonged stable disease, showing that TPST-1120 has activity as a monotherapy
    - Two patients with IDH1 mutated CCA, a mutation found in ~15-30% of intrahepatic CCA, had stable disease extending out to five and ten months, respectively, vs. less than three months for historical standard-of-care values, indicating that an IDH1 mutation is a potential biomarker for patient sensitivity to TPST-1120
- In the combination arm, two patients with renal cell carcinoma (RCC) and one with metastatic CCA achieved partial response when treated with the higher doses of TPST-1120 in combination with pembrolizumab
    - Both RCC patients had progressed on prior anti-PD1 therapy, providing strong evidence that TPST-1120 overcomes resistance to anti-PD1 therapy
    - The patient with metastatic CCA had received multiple lines of prior systemic therapy and was PDL1-negative, mismatch repair proficient, and had a TMB of less than 10 mutations per megabase, supporting that TPST-1120 can reprogram the TME in immune-resistant type cancers

TPST-1120 Monotherapy Results

In the monotherapy portion of the trial, 19 evaluable patients with late-line treatment-refractory solid tumors, including pancreatic, cholangiocarcinoma, 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 evaluable patients with heavily-pretreated renal cell carcinoma, 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.

Financial Update

Following the $15 million private investment in public equity financing completed in April 2022, Tempest's cash and cash equivalents are currently expected to be sufficient to fund its current operating plans into the first quarter of 2024.

About TPST-1120

TPST-1120 is a first-in-class[1] 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 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.

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, a DNA repair enzyme that controls activation of 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 about the design, progress, timing, scope and results of clinical trials, the benefits that may be derived from any product candidates, or the company's expected cash runway. 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: success in clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials; 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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[1] If approved by the FDA