Tempest Therapeutics Inc

Fact Sheet

T P S T

LISTED

NASDAQ

TEMPEST THERAPEUTICS

QUICK REFERENCE

Tempest Therapeutics
NASDAQ: TPST
www.TEMPESTTX.com

BUSINESS SUMMARY

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 has a diverse portfolio of novel programs ranging from early research to investigation in a randomized global study in first-line cancer patients. The company's two clinical programs, TPST-1120 and TPST-1495, target PPARα and the prostaglandin E2 receptors, EP2/EP4, respectively, and are advancing through trials designed to study the agents as monotherapies and in combination with approved agents. Tempest is also developing an orally available inhibitor of TREX1, a target that controls activation of the cGAS/STING pathway.

SCIENCE

PPARα ANTAGONISM

Peroxisome proliferator-activated receptor alpha (PPARα) is a transcription factor that regulates fatty acid oxidation (FAO) and inflammation and is highly expressed by many cancers, including hepatocellular carcinoma (HCC) and cholangiocarcinoma (CCA) to a significant degree. TPST-1120 has completed monotherapy dose escalation, and is progressing through a Phase 1/1b study in combination with nivolumab (NCT03829436) and a randomized Phase 1b/2 study in combination with atezolizumab (TECENTRIQ®) and bevacizumab (Avastin®) in frontline patients with advanced hepatocellular carcinoma (HCC) pursuant to a collaboration with F. Hoffmann-La Roche Ltd.

DUAL EP2/EP4 ANTAGONSIM

EP2 and EP4 are two receptors in the prostaglandin (PGE2) signaling pathway promoting both tumor-growth and immune suppression, and are expressed together by many cancers, including colorectal and endometrial cancers. TPST-1495 is progressing through Phase 1/1b monotherapy and combination studies.

TREX-1 INHIBITOR

The exonuclease TREX-1 is the sentinel of cytosolic dsDNA and dampens the activation of cGAS/STING to avoid immune recognition. Inhibition of TREX-1 results in enhanced activation of STING and Interferon (IFN) β, leading to induction of tumor-specific immunity. Tempest is currently moving the program through lead optimization.

PIPELINE

Tempest is developing a first-in-class oncology pipeline of small molecule therapeutics with broad commercial potential. The product candidates are designed to treat cancer by direct tumor killing, activating tumor-specific immunity, or a combination of both mechanisms.

For development pipeline details visit: **https://www.tempesttx.com/pipeline/**

CONTACT INFORMATION

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Recent Press Releases *(Headlines and Excerpts)*

Tempest Announces Expanded Role for Sam Whiting, M.D., Ph.D., as Chief Medical Officer and Head of Research and Development

Sept. 19, 2023 -- Tempest Therapeutics, Inc. announced today that executive vice president and chief medical officer, Sam Whiting, M.D. Ph.D., has expanded his role to include head of Research and Development.

Dr. Whiting joined Tempest as executive vice president and chief medical officer in November 2020, and assumed the role of chief medical officer and head of research and development following the departure of Tom Dubensky, Ph.D., who has become an advisor to the company. Prior to joining Tempest, Dr. Whiting served as senior vice president of clinical development at Calithera Biosciences, a clinical-stage biotech company focused on developing treatments for cancer and other life-threatening diseases. Before Calithera, Dr. Whiting served as vice president of research and clinical development at Gradalis and worked in development of small molecule targeted and immune-oncology agents at VentiRx Pharmaceuticals and Oncothyreon. Prior to joining industry, Dr. Whiting served as assistant professor of medical oncology at the University of Washington, assistant member of clinical research at the Fred Hutchinson Cancer Research Center, and clinical head of gastrointestinal oncology at the Seattle Cancer Care Alliance. Dr. Whiting completed fellowship training in medical oncology at the Fred Hutchinson Cancer Research Center. His training in internal medicine was through the ABIM Research Pathway at the University of Washington. Dr. Whiting received his B.S. with Honors in Chemistry from Lewis and Clark College and his M.D. and Ph.D in microbiology in the Medical Scientist Training Program at the University of Washington.

Tempest Reports Second Quarter 2023 Financial Results and Provides Business Update

Aug. 10, 2023 -- Tempest Therapeutics, Inc. reported financial results for the quarter ended June 30, 2023 and provided a corporate update.

Recent Highlights

- TPST-1120 (clinical PPARα antagonist): announced positive early results from the ongoing randomized first-line HCC study comparing TPST-1120 combined with the standard-of-care regimen of atezolizumab and bevacizumab, with head-to-head to standard-of-care alone. The data were positive in multiple categories, and demonstrated a favorable safety profile:
    - Unconfirmed responses of 30% for the TPST-1120 triplet arm (12/40) vs. 17.2% for the active control arm (5/29), demonstrating a 74.4% relative improvement in objective response rate (ORR);
    - Confirmed responses of 17.5% for the TPST-1120 triplet arm (7/40) vs. 10.3% for the active control arm (3/29), demonstrating a 69.9% relative improvement in confirmed ORR;
    - 47.5% (19/40) of the TPST-1120 arm patients are on treatment vs. 23.3% (7/30) in the control arm; and
    - 80% (32/40) of the TPST-1120 arm patients are on study vs. 50% (15/30) in the control.ii
- TPST-1495 (clinical dual EP2/4 prostaglandin receptor antagonist): (i) presented data from a Phase 1 study evaluating TPST-1495 as a monotherapy and in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab in advanced solid tumors at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; (ii) published mechanism of action data highlighting the increased potency of the molecule against prostaglandin-driven tumor models in Cancer Research Communications, a journal of the American Association for Cancer Research; and (iii) continued enrollment of an endometrial cancer-specific arm investigating the two highest doses of TPST-1495 in combination with pembrolizumab.

Potential Upcoming Milestones

- TPST-1120 (clinical PPARα antagonist): we expect to be able to discuss an updated and comprehensive data set from the formal review of the ongoing, global, randomized Phase 1b/2 study in first-line liver cancer patients in the second half of 2023.
- TPST-1495 (clinical dual EP2/4 prostaglandin receptor antagonist): we plan to report data from the combination arm at the two highest TPST-1495 doses in patients with advanced endometrial cancer in 2024.
- TREX1 Inhibitor (preclinical tumor-selective STING pathway activator): we expect to advance new proprietary small molecule series TREX1 inhibitors generated through insights resulting from human TREX1-inhibitor co-crystal structures.

Tempest Announces Publication in Cancer Research Communications Highlighting the Significantly Increased Potency of TPST-1495 Against Prostaglandin-Driven Tumor Models by Blocking EP2 and EP4 Together

- ***In vitro and in vivo data show significant increased potency by blocking prostaglandin PGE2 signaling through both EP2 and EP4 receptors compared to celecoxib or single EP4 antagonists***
- ***TPST-1495 anti-tumor response shown to be both immune dependent and immune independent***
- ***Preclinical findings support previously reported Phase 1 clinical results for TPST-1495 showing tumor shrinkage and prolonged disease control in both monotherapy and in combination with pembrolizumab***

July 19, 2023 -- Tempest Therapeutics, Inc. announced today that in vivo and in vitro data on the unique mechanism of TPST-1495, the company's novel dual receptor inhibitor of prostaglandin E2 (PGE2) signaling, were published in Cancer Research Communications, a journal of the American Association for Cancer Research.

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