Tempest Therapeutics Announces First Patient Dosed with the Combination of TPST-1120 Plus Nivolumab in a Phase 1 Study in Patients with Advanced Solid Tumors

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– Combination regimen will treat patients with cholangiocarcinoma, liver and kidney cancers

– First step in broader combination strategy given TPST-1120's novel mechanism of action

South San Francisco, CA – June 22 2020 - Tempest Therapeutics, Inc., a clinical-stage oncology company developing first-in-class therapeutics that combine both precision and immune-mediated mechanisms, today announced that the first patient has been dosed with TPST-1120 plus nivolumab in the combination dose escalation portion of the Phase 1 trial of TPST-1120. This portion of the study will enroll patients with advanced hepatocellular carcinoma, renal cell carcinoma, and cholangiocarcinoma.

"TPST-1120 has an interesting dual mechanism, designed to both attack malignant cells directly and enable the immune system to fight the tumor," said Johanna Bendell, MD, Chief Development Officer and Director, Drug Development Unit Nashville, Sarah Cannon Research Institute at Tennessee Oncology. "This type of anti-cancer approach could represent an important therapeutic option for patients, and I'm looking forward to evaluating the combination with nivolumab in this study."

"After seeing initial signs of clinical benefit and biomarker modulation with TPST-1120 as a monotherapy, we are pleased to expand into the first combination setting, in this case, with nivolumab," said Stephen Brady, president and chief operating officer of Tempest. "As a PPAR α antagonist, there is a strong mechanistic rationale to combine TPST-1120 with multiple systemtic anti-cancer modalities, such as an anti-PD-1/L1 antibody and anti-angiogensis agents."

The first-in-human Phase 1/1b, multicenter, open-label, dose-escalation and dose-expansion study is evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity in patients with select advanced solid tumors. The trial is being conducted in approximately fifteen sites across the U.S. Tempest will continue to enroll patients in the dose escalation monotherapy arm, as well. For additional information about the trial, please visit www.clinicaltrials.gov, identifier NCT03829436.

About TPST-1120

TPST-1120 is a first-in-class selective PPARα antagonist with a two-pronged 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. In multiple animal 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. As a monotherapy in the clinic, TPST-1120 has shown early signs of tumor control and biomarker modulation

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage oncology company advancing small molecules that combine both precision and immune-mediated mechanisms to modulate anti-tumor pathways with the potential to target a wide range of tumors. The company's two novel clinical programs are TPST-1120 and TPST-1495, antagonists of PPARα and EP2/4, respectively. Both TPST-1120 and TPST-1495 are progressing through Phase 1 studies designed to study both agents as monotherapies and in combination with other approved agents. Tempest is also developing an inhibitor of TREX-1, an exonuclease highly expressed in tumors that suppresses both STING and tumor immunity, to activate STING selectively in metastatic lesions via a systemically-delivered small molecule. 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.

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