Tempest Therapeutics Announces Clinical Collaboration with Roche to Advance TPST-1120 into a Randomized Combination Study in First-line Hepatocellular Carcinoma

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– TPST-1120/atezolizumab/bevacizumab triplet will be compared to atezolizumab/bevacizumab alone

South San Francisco, CA – March 3, 2021 - Tempest Therapeutics, Inc., a clinical-stage oncology company developing first-in-class therapeutics that combine both precision and immune-mediated mechanisms, today announced a clinical collaboration agreement with F. Hoffmann-La Roche Ltd. The collaboration will evaluate TPST-1120, Tempest's small molecule PPAR α antagonist, in combination with atezolizumab (Tecentriq®) and bevacizumab (Avastin®) in previously untreated patients with advanced hepatocellular carcinoma (HCC).

"We are thrilled to work with Roche to accelerate the TPST-1120 program by evaluating this molecule in a targeted front-line clinical setting," said Stephen Brady, president and chief operating officer of Tempest. "TPST-1120's mechanism of action makes it specifically well-suited to combine with both PD-1/PD-L1 checkpoint inhibitors and anti-angiogenesis agents. This strong scientific rationale, coupled with the observed clinical safety profile and early signals of clinical benefit in treated patients, makes us hopeful that this triplet approach will offer HCC patients meaningful benefit."

TPST-1120 will be evaluated in a global randomized phase 1b/2 clinical study in combination with the standard-of-care first-line regimen of atezolizumab and bevacizumab in patients with advanced or metastatic HCC not previously treated with systemic therapy. Up to 60 patients will receive the TPST-1120 combination 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 will retain global development and commercialization rights to TPST-1120.

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, 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 early signs of tumor reduction and control, 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, with the majority of cases in Asia and almost half of all cases in China. 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 precision and immune-mediated mechanisms with the potential to target 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 inhibitor of TREX-1, an exonuclease with enhanced expression in tumors that suppresses activation of the cGAS/STING pathway by degrading cytosolic DNA. Oral delivery of a TREX-1 small molecule inhibitor is intended to selectively activate STING in tumors, leading to anti-tumor immunity. 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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