



Tempest Therapeutics Starts Phase I/Ib Clinical Trial with First-in-Class PPAR Alpha Antagonist

--Company strengthens board of directors and scientific advisory board with appointments of Mike Raab and Benjamin Cravatt--

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SAN FRANCISCO--([BUSINESS WIRE](#))--Tempest Therapeutics Inc., a clinical-stage biotechnology company developing a broad portfolio of first-in-class immunomodulatory small molecules targeting diverse cancers, today announced that the first patient has been dosed with TPST-1120 in a Phase I/Ib trial to treat advanced solid tumor malignancies.

PPAR (peroxisome proliferator-activated receptor) alpha is a nuclear transcription factor that regulates fatty acid oxidation and lipid metabolism in the tumor microenvironment (TME). TPST-1120 is a PPAR alpha antagonist that has a two-pronged mechanism, targeting both tumor cells and suppressive immune cells in the TME dependent on fatty acid metabolism, driving a metabolic shift to glycolysis and facilitating the development of a tumor-specific effector immune cell response. In extensive animal studies, TPST-1120 therapy used as a single agent or in combination with other anti-cancer drugs resulted in significant reductions in tumor growth and stimulation of durable anti-tumor immunity.

The U.S. Phase I trial (NCT03829436) is enrolling patients with advanced solid tumors. The open-label, dose-escalation and dose-expansion study is testing oral twice-daily TPST-1120 as monotherapy and in combination with marketed cancer drugs such as PD-1 inhibitors, anti-EGFR antibodies or chemotherapy. Primary outcome measures of the trial include assessing safety and tolerability and establishing a dose range for expanded studies at specified TPST-1120 doses. Secondary outcome measures include pharmacokinetics, mechanism-based biomarkers and objective response rate.

"Today represents an exciting moment for Tempest, as we transition to a clinical-stage company that is advancing first-in-human therapies targeting new pathways to induce anti-cancer immunity. Ultimately, we hope that our new approaches to treat cancer will provide benefit to patients," said Ginna Laport, MD, CMO of Tempest.

To help facilitate the transition to a clinical-stage company, Tempest has made key appointments to its board of directors with the appointment of Mike Raab, and to its scientific advisory board with the appointment of Benjamin Cravatt, Ph.D.

Mr. Raab is president and CEO of Ardelyx Inc., a publicly traded biotechnology company focused on cardiorenal diseases. He previously was a partner at New Enterprise Associates, where he spent 15 years in commercial and operating leadership roles in the biotech and pharmaceutical industries. Before NEA, he was SVP of therapeutics and general manager of the renal division at Genzyme Corp. where he launched and oversaw the sales growth of sevelamer, the leading phosphate binder to treat hyperphosphatemia, with over \$1 billion in worldwide sales in 2013. Mike also was instrumental in the worldwide launch of Genzyme's therapies for Gaucher disease, Ceredase and Cerezyme.

Dr. Cravatt is a professor in the Skaggs Institute for Chemical Biology and Gilula Chair Chemical Biology at The Scripps Research Institute. His research group is interested in understanding the roles that enzymes play in physiological and pathological processes, especially as pertains to the nervous system and cancer. Dr. Cravatt is a co-founder and scientific advisor of multiple biotechnology companies.

“Mike Raab and Ben Cravatt are widely recognized leaders in pharma and biotechnology drug development, and each will provide significant guidance and insights to facilitate Tempest’s continuing success,” said Tom Dubensky, Ph.D., president and CEO of Tempest.

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage biotechnology company advancing small molecules that modulate anti-tumor immunity pathways. The company has a balanced and deep pipeline consisting of first-in-class and potential best-in-class small molecule therapeutics that modulate distinct immune response pathways relevant to mounting an effective anti-tumor response. Tempest’s backers include Versant Ventures, F-Prime Capital, Quan Capital, Lilly Asia Ventures, Foresite Capital and Eight Roads Ventures.

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