



Turning Point Therapeutics Initiates Global Phase 1/2 Forge-1 Clinical Study of TPX-0131, a Next-Generation ALK Inhibitor

April 12, 2021

Investigational New Drug Application Cleared

Study Initiated in Australia, with U.S. Site Activations Now Planned

SAN DIEGO, April 12, 2021 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing next-generation therapies that target genetic drivers of cancer, today announced initiation of its Phase 1/2 FORGE-1 study of TPX-0131, a potent inhibitor of the anaplastic lymphoma kinase (ALK) and multiple resistant mutations of ALK.

The investigational new drug (IND) application for TPX-0131 is Turning Point's third IND to be cleared by the FDA in less than 2 years, and FORGE-1 is the company's fourth clinical study to initiate during the same period of time.

The study was initiated in Australia, with U.S. site activations now planned.

"With a lack of available therapies to address a broad spectrum of ALK resistant mutations, we are encouraged by the preclinical potency for TPX-0131, particularly against the G1202R solvent front mutation which is reported to occur in more than 40% of biopsies with resistance mutations," said Ben Solomon, M.D., principal investigator for the FORGE-1 study, a medical oncologist and group leader of the Molecular Therapeutics and Biomarkers Laboratory at the Peter MacCallum Cancer Centre in Melbourne, Australia. "In addition, TPX-0131 has been shown preclinically to penetrate the central nervous system, which is important in the treatment of patients with ALK-positive non-small cell lung cancer as the disease often progresses in the brain."

ALK alterations are estimated to be responsible for 3% to 5% of non-small cell lung cancer (NSCLC) cases annually in the U.S. and EU5 countries. In preclinical studies, TPX-0131 potently inhibits wildtype ALK and is more potent in comparison to approved ALK inhibitors against many clinically observed resistance mutations, including the G1202R solvent front mutation, L1196M gatekeeper mutation, and multiple compound mutations. In addition, TPX-0131 has shown brain tissue penetration after repeat oral dosing.

"Our clinical study of TPX-0131 will begin with a Phase 1 dose finding portion in patients previously treated with up to 2 prior ALK tyrosine kinase inhibitors, a population we believe is underserved today by available therapies that are less potent against known resistant mutations of ALK," said Mohammad Hirmand, M.D., chief medical officer of Turning Point Therapeutics.

The Phase 1 dose finding portion of the FORGE-1 study will enroll patients with locally advanced or metastatic TKI-pretreated ALK-positive NSCLC. Patients with up to 2 prior ALK TKIs and 1 prior platinum-based chemotherapy will be enrolled. The study endpoints include safety and tolerability, determination of the maximum tolerated dose and/or the recommended Phase 2 dose, and objective response rate by RECIST 1.1.

About Turning Point Therapeutics Inc.

Turning Point Therapeutics is a clinical-stage precision oncology company with a pipeline of internally discovered investigational drugs designed to address key limitations of existing cancer therapies. The company's lead drug candidate, repotrectinib, is a next-generation kinase inhibitor targeting the ROS1 and TRK oncogenic drivers of non-small cell lung cancer and advanced solid tumors. Repotrectinib, which is being studied in a registrational Phase 2 study in adults and a Phase 1/2 study in pediatric patients, has shown antitumor activity and durable responses among kinase inhibitor treatment-naïve and pre-treated patients. The company's pipeline of drug candidates also includes TPX-0022, targeting MET, CSF1R and SRC, which is being studied in a Phase 1 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in MET; TPX-0046, targeting RET, which is being studied in a Phase 1/2 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in RET; and TPX-0131, a next-generation ALK inhibitor, which is being studied in a Phase 1/2 trial of previously treated patients with ALK-positive advanced or metastatic non-small cell lung cancer. Turning Point's next-generation kinase inhibitors are designed to bind to their targets with greater precision and affinity than existing therapies, with a novel, compact structure that has demonstrated an ability to potentially overcome treatment resistance common with other kinase inhibitors. The company is driven to develop therapies that mark a turning point for patients in their cancer treatment. For more information, visit www.tgetherapeutics.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and therapeutic potential of Turning Point Therapeutics' drug candidate TPX-0131, the results, conduct, progress and timing of Turning Point Therapeutics' pre-clinical studies and clinical trials and plans regarding future clinical trials. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans", "will", "believes," "anticipates," "expects," "intends," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Turning Point Therapeutics' current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Turning Point Therapeutics' business in general, risks and uncertainties related to the impact of the COVID-19 pandemic to Turning Point's business and the other risks described in Turning Point Therapeutics' filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Turning Point Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contact:
Jim Mazzola
jim.mazzola@tptherapeutics.com
858-342-8272



Source: Turning Point Therapeutics, Inc.