Turning Point Therapeutics Initiates Phase 1/2 Clinical Study of Repotrectinib in Pediatric Patients

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SAN DIEGO, Nov. 12, 2019 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing novel drugs to address treatment resistance, today announced initiation of a Phase 1/2 clinical study of its lead drug candidate repotrectinib in pediatric patients with *ALK*-, *NTRK*- and *ROS1*-positive solid tumors.

"The initiation of our study in pediatric cancer patients expands the clinical development of our internally discovered and wholly owned pipeline of kinase inhibitors, now with three drug candidates in four clinical trials," said Athena Countouriotis, M.D., president and CEO. "The pediatric study is an important milestone for Turning Point Therapeutics as we advance our work one step closer to bringing our targeted drug candidates to patients with oncogenic-driven cancers."

The study is anticipated to enroll approximately 12 patients in a Phase 1 dose-escalation portion and approximately 63 patients across three cohorts in a Phase 2 dose-expansion portion to assess *NTRK*-positive TKI-naïve tumors, *NTRK*-positive TKI-pretreated tumors, and *ALK*- or *ROS1*-positive tumors.

Repotrectinib is Turning Point Therapeutics' lead drug candidate, already being studied in a global registrational Phase 2 study. The new Phase 1/2 study is an open-label single-arm, multi-center clinical trial to evaluate the safety, tolerability, PK, and preliminary efficacy of repotrectinib in pediatric and young adult patients with advanced or metastatic solid tumors, primary CNS tumors, or anaplastic large cell lymphoma (ALCL) with *ALK*, *ROS1*, or *NTRK* alterations.

Repotrectinib is an investigational next-generation TKI designed to target ROS1, TRK A/B/C, and ALK, and systemically overcome resistant mutations that result following treatment with other TKIs.

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 program, repotrectinib, is a next-generation kinase inhibitor targeting genetic drivers of non-small cell lung cancer and advanced solid tumors. Repotrectinib, which is currently 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 currently being studied in a Phase 1 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in *MET*; and TPX-0046, targeting RET and SRC, which is currently being studied in a Phase 1/2 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in *RET*. Turning Point's 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.tptherapeutics.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 repotrectinib, the results, conduct and timing of Turning Point Therapeutics' 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, 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.

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