# Turning Point Therapeutics Granted FDA Breakthrough Therapy Designation for Repotrectinib Treatment in Patients with ROS1-Positive Metastatic Non-Small Cell Lung Cancer Who Have Not Been Treated with a ROS1 Tyrosine Kinase Inhibitor

December 8, 2020

**Updated Data from TRIDENT-1 Study in TKI-Naive Patients with ROS1-Positive Non-Small Cell Lung Cancer Planned for Presentation at Upcoming World Conference on Lung Cancer**

SAN DIEGO, Dec. 08, 2020 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing next-generation therapies that target genetic drivers of cancer, today announced its lead drug candidate, repotrectinib, has been granted breakthrough therapy designation by the Food and Drug Administration (FDA) for the treatment of patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC) who have not been treated with a ROS1 tyrosine kinase inhibitor (TKI-naïve).

“Breakthrough therapy designation is another milestone in our development of repotrectinib and one more step towards our goal to get this potentially important drug candidate to patients as quickly as possible,” said Athena Countouriotis, M.D., president and chief executive officer. “I am incredibly proud of our Turning Point team with the achievement of our fourth regulatory designation from the FDA for repotrectinib, and pleased with how our enrollment specifically in the ROS1 TKI-naive population of the TRIDENT-1 study has progressed since we reported initial early Phase 2 data. We look forward to sharing more information on our overall study timelines early next year, and providing updated data from the TRIDENT-1 study next month.”

Turning Point plans to present updated TRIDENT-1 Phase 2 study data from patients with TKI-naive ROS1-positive NSCLC during a mini-oral presentation at the World Conference on Lung Cancer on Jan. 31, 2021.

The breakthrough therapy designation for repotrectinib was supported by the initial data from TKI-naïve ROS1-positive NSCLC patients enrolled in the Phase 1 and Phase 2 portions of the TRIDENT-1 study, which is currently evaluating patients in multiple potentially registrational cohorts.

Breakthrough therapy designation is granted by the FDA to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. Repotrectinib was previously granted three Fast Track designations by the FDA, in ROS1-positive NSCLC patients who are TKI naïve, ROS1-positive NSCLC patients who have been previously treated with one prior platinum chemotherapy and one prior ROS1 TKI, and NTRK-positive patients with advanced solid tumors who have progressed following treatment with at least one prior line of chemotherapy and one or two prior TRK 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 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 called TRIDENT-1 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 in a Phase 1 study called SHIELD-1 in patients with advanced or metastatic solid tumors harboring genetic alterations in *MET*; RET-inhibitor TPX-0046, which is in a Phase 1/2 study of patients with advanced or metastatic solid tumors harboring genetic alterations in *RET*; and ALK-inhibitor TPX-0131, which is in IND-enabling studies. 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.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 Turning Point Therapeutics’ drug candidate repotrectinib, the results, conduct, progress and timing of Turning Point Therapeutics’ development programs, and the regulatory approval path for repotrectinib. 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.