Turning Point Therapeutics Granted Breakthrough Therapy Designation for Repotrectinib Treatment in Patients with NTRK-Positive, TKI-Pretreated Advanced Solid Tumors

October 4, 2021

SAN DIEGO, Oct. 04, 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 the U.S. Food and Drug Administration (FDA) granted a seventh regulatory designation to lead drug candidate, repotrectinib.

Breakthrough Therapy designation was granted for the treatment of patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with one or two prior TRK tyrosine kinase inhibitors, with or without prior chemotherapy, and have no satisfactory alternative treatments. The company is planning to discuss next steps towards potential registration of repotrectinib in this patient population at a Type B meeting with the FDA anticipated in the first half of 2022.

“We are excited to receive our second Breakthrough Therapy designation and seventh overall regulatory designation for repotrectinib,” said Athena Countouriotis, M.D., president and chief executive officer. “There remains an unmet medical need for NTRK-positive, TKI-pretreated advanced solid tumor patients where there are no targeted therapies currently approved. We look forward to presenting additional clinical data from our TRIDENT-1 study of repotrectinib during the AACR-NCI-EORTC conference later this week, including a late-breaker plenary presentation where early clinical data from the NTRK EXP-5 and EXP-6 cohorts will be discussed.”

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 Breakthrough Therapy designation in ROS1- positive metastatic non-small cell lung cancer (NSCLC) patients who have not been treated with a ROS1 tyrosine kinase inhibitor, as well as four Fast-Track designations in: ROS1-positive advanced NSCLC patients who are ROS1 TKI naïve; ROS1-positive advanced NSCLC patients who have been previously treated with one prior line of platinum-based chemotherapy and one prior ROS1 TKI; ROS1-positive advanced NSCLC patients pretreated with one prior ROS1 TKI without prior platinum-based chemotherapy; 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 and have no satisfactory alternative treatments. Repotrectinib was also granted an Orphan Drug designation in 2017.

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.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, progress and timing of the repotrectinib development program, 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, including its quarterly report on Form 10-Q filed with the SEC on August 9, 2021. 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:
Scott Lipman
ir@tptherapeutics.com
858-876-3985

Source: Turning Point Therapeutics, Inc.