Turning Point Therapeutics Granted Breakthrough Therapy Designation for Repotrectinib Treatment in Patients With One Prior ROS1 Tyrosine Kinase Inhibitor and no Prior Chemotherapy

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SAN DIEGO, May 10, 2022 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a clinical-stage precision oncology company designing and developing novel targeted therapies for cancer treatment, today announced the U.S. Food and Drug Administration (FDA) granted an eighth regulatory designation, and third Breakthrough Therapy designation, to lead drug candidate repotrectinib.

Breakthrough Therapy designation (BTD) was granted for the treatment of patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC) who have been previously treated with one ROS1 tyrosine kinase inhibitor and who have not received prior platinum-based chemotherapy. The efficacy analyses supporting the BTD application included approximately 50 patients pooled from the Phase 1 and Phase 2 portions of the TRIDENT-1 study. Efficacy evaluations in Phase 2 patients were by physician assessment.

“We are excited to receive our third BTD and eighth overall FDA regulatory designation for repotrectinib in an indication where there are no approved targeted therapies,” said Mohammad Hirmand, M.D., Chief Medical Officer. “We are encouraged by the continued momentum in TRIDENT-1 with enrollment targets achieved in cohorts EXP-1, EXP-4 and EXP-6. We look forward to continuing to progress repotrectinib toward registration with our first pre-NDA meeting with the FDA to discuss the topline data by blinded independent central review from the ROS1-positive advanced NSCLC cohorts of the TRIDENT-1 study expected later this quarter.”

BTD 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 BTD 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 two BTDs in: ROS1-positive metastatic NSCLC patients who have not been treated with a ROS1 tyrosine kinase inhibitor, and 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. Repotrectinib was also previously granted 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.

Enrollment across all six cohorts of the study remains open and continues to progress steadily.

About Turning Point Therapeutics Inc.
Turning Point Therapeutics is a clinical-stage precision oncology company with a pipeline of 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 elzovantinib, 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; 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; and TPX-4589 (LM-302), a novel ADC targeting Claudin18.2 being studied in a Phase 1 study in gastrointestinal cancers. 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 momentum in TRIDENT-1 study, the ability to continue to progress repotrectinib toward registration, timing of Turning Point Therapeutics’ first pre-NDA meeting with the FDA to discuss the topline data by blinded independent central review from the ROS1-positive advanced NSCLC cohorts of the TRIDENT-1 study, the potential benefits of BTD, progression of enrollment, and the efficacy and therapeutic potential of 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 Securities and Exchange Commission (SEC), including its annual report on Form 10-K filed with the SEC on February 28, 2022. 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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