Turning Point Therapeutics Granted Fast-Track Designation for Repotrectinib in NTRK-Positive TKI-Pretreated Advanced Solid Tumors

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SAN DIEGO, Aug. 24, 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 the Food and Drug Administration (FDA) granted a third Fast-Track designation to its lead drug candidate, repotrectinib.

The designation was granted for the treatment of patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with at least one prior line of chemotherapy and one or two prior TRK tyrosine kinase inhibitors (TKIs) and have no satisfactory alternative treatments. Repotrectinib was previously granted two Fast Track designations for the treatment of *ROS1*-positive advanced non-small cell lung cancer patients, first for patients with one prior line of platinum-based chemotherapy and one prior ROS1 TKI, and second for patients without prior ROS1 TKI treatment. There are no approved targeted therapies for patients previously treated with another ROS1 or TRK TKI.

“We believe repotrectinib has the potential to make a meaningful difference in the lives of cancer patients with ROS1- or NTRK-driven tumors and are pleased to receive our third Fast-Track designation that may help expedite its development,” said Athena Countouriotis, M.D., president and chief executive officer. “NTRK-driven cancers are estimated to occur in up to 50,000 patients annually, however there are currently no approved therapies for those patients previously treated with another TRK TKI.”

Turning Point recently reported early interim data from its registrational Phase 2 TRIDENT-1 study of repotrectinib, showing a confirmed objective response rate of 50 percent (3/6) in the cohort of NTRK-positive TKI-pretreated advanced solid tumor patients. A total of 40 patients are planned for enrollment in this cohort, and the FDA recently provided guidance that 6 months of follow up from the last response in this cohort may be sufficient to support potential approval. Previous guidance was 12 months. This recent guidance and Fast-Track designation may provide a faster path to potential approval.

About Fast Track Designation
Fast Track is an FDA program intended to facilitate the development and expedite the review of drug candidates to treat serious conditions and fill an unmet medical need.

A drug candidate that receives Fast Trackdesignation may be eligible for:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communication with FDA;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met;
- Rolling submission of a New Drug Application (NDA) for review by FDA.

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 and SRC, 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 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 repotrectinib, the results, conduct, progress and timing of the TRIDENT-1 clinical study, plans regarding future regulatory submissions 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