Turning Point Therapeutics Granted Sixth Regulatory Designation for Repotrectinib

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Fast-Track Designation Granted by FDA in ROS1-Positive Advanced Non-Small Cell Lung Cancer Patients Pretreated With One Prior ROS1 Tyrosine Kinase Inhibitor Without Prior Chemotherapy

SAN DIEGO, Aug. 11, 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 sixth regulatory designation to lead drug candidate, repotrectinib.

The Fast-Track designation was granted for the treatment of patients with ROS1-positive advanced non-small cell lung cancer (NSCLC) who have been previously treated with one prior ROS1 tyrosine kinase inhibitor (TKI) and who have not received prior platinum-based chemotherapy.

“We are pleased to receive our fourth Fast-Track designation and sixth overall regulatory designation for repotrectinib as we continue to work toward our goal of getting this ROS1 targeted therapy to patients quickly,” said Athena Countouriotis, M.D., president and chief executive officer. “We continue to believe repotrectinib has the potential to be a best-in-class treatment for patients with ROS1-positive advanced non-small cell lung cancer or NTRK-positive advanced solid tumors and now have multiple regulatory designations in both the TKI-naïve and TKI-pretreated ROS1 patient populations.”

Repotrectinib was previously granted Breakthrough Therapy designation in ROS1- positive metastatic NSCLC patients who have not been treated with a ROS1 tyrosine kinase inhibitor, as well as three 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, 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.

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-Track designation may be eligible for:

- More frequent meetings with the FDA to discuss the drug’s development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communication with the FDA;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and
- 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, 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 potential benefits of Fast Track Designation 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.

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