



## Turning Point Therapeutics Provides Regulatory Update for Repotrectinib for the Treatment of ROS1+ Advanced NSCLC

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### Completed pre-NDA meeting to discuss proposed patient follow-up in ROS1+ advanced NSCLC with FDA

SAN DIEGO, July 27, 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 receipt of positive feedback from the U.S. Food and Drug Administration (FDA) at a pre-New Drug Application (NDA) meeting completed within the second quarter. The feedback focused on the planned patient follow-up within the ROS1+ advanced non-small cell lung cancer (NSCLC) patient cohorts of the ongoing TRIDENT-1 registrational study of repotrectinib, the company's lead drug candidate, which is a potential best-in-class ROS1 tyrosine kinase inhibitor that has received two breakthrough therapy designations within ROS1+ advanced NSCLC.

The purpose of the pre-NDA meeting was to discuss the company's planned NDA for repotrectinib for the treatment of ROS1+ advanced NSCLC. The FDA agreed with the company's plan to provide data for ROS1+ TKI-naïve and TKI-pretreated advanced NSCLC patients with at least six months of follow-up from the first post-baseline scan at the time of NDA submission.

"We continue to be encouraged by our collaborative meetings with the FDA," said Mohammad Hirmand, M.D., Chief Medical Officer. "The planned NDA submission represents an important milestone for our company. The unmet need in ROS1+ advanced NSCLC patients is significant, and we continue to believe that repotrectinib could offer a best-in-class profile for the treatment of these patients."

#### 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 elzoventinib, 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](http://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 anticipated timing for completing an NDA submission for repotrectinib for the treatment of ROS1+ advanced NSCLC, and the potential best-in-class profile 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 quarterly report on Form 10-Q filed with the SEC on May 10, 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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