Turning Point Therapeutics Granted FDA Orphan Drug Designation for TPX-0022 in Gastric Cancer

June 17, 2021

SAN DIEGO, June 17, 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 that TPX-0022, the company's inhibitor of MET and the associated cancer signaling pathways of SRC and CSF1R, has been granted orphan drug designation by the Food and Drug Administration (FDA) for the treatment of patients with gastric cancer, including gastroesophageal junction adenocarcinoma.

"Aberrant signaling and genomic alterations in MET-driven gastric cancers are associated with a poor prognosis for patients, creating a high unmet need for therapies to target the molecular drivers of the disease," said Mohammad Hirmand, M.D., chief medical officer. "We are pleased to receive this designation for TPX-0022 as we work to develop it as a potentially differentiated option for patients affected by MET-driven gastric cancer."

There are currently no approved MET inhibitors for the treatment of gastric cancer and gastroesophageal junction adenocarcinoma.

TPX-0022 is a potent inhibitor of the MET tyrosine kinase and has the potential to modulate the tumor microenvironment to augment its therapeutic effect. Initial clinical data presented from the ongoing Phase 1 SHIELD-1 study in October 2020 showed TPX-0022 has been generally well-tolerated and demonstrated clinical activity in patients with MET-amplified gastric cancer.

Orphan Drug Designation is granted by the FDA to assist in the development of drug candidates that may offer therapeutic benefits for diseases with a prevalence of fewer than 200,000 patients annually. Benefits of the designation may include the opportunity for accelerated approval, discounts on registration fees, tax credits for qualified clinical trials and eligibility for 7 years of market exclusivity post-regulatory approval.

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. 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. Such forward-looking statements in this press release include statements regarding, among other things, the efficacy, safety and therapeutic potential of TPX-0022, the results of the SHIELD-1 clinical study, and the potential benefits of Orphan Drug Designation. 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 May 5, 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:
Jim Mazzola
jim.mazzola@tptherapeutics.com
858-342-8272

Source: Turning Point Therapeutics, Inc.