Turning Point Therapeutics Announces FDA Clearance of Investigational New Drug Application for TPX-0046, a Novel RET/SRC Inhibitor

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SAN DIEGO, Sept. 30, 2019 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing novel drugs to address treatment resistance, today announced clearance by the U.S. Food and Drug Administration (FDA) of its investigational new drug application (IND) for TPX-0046, a novel therapy targeting solid tumors with abnormal RET genes by inhibiting RET and SRC kinases.

Under the IND, the company plans to initiate a Phase 1/2 first-in-human, open-label clinical study later this year. The phase 1 portion will have a dose-finding design, including intra-patient dose escalation to assess the safety, tolerability, and preliminary clinical activity of TPX-0046 in patients with advanced or metastatic solid tumors harboring oncogenic RET fusions or mutations. The phase 2 portion will evaluate the preliminary efficacy of TPX-0046 in multiple cohorts of patients with advanced or metastatic sold tumors harboring oncogenic RET fusions or mutations.

“TPX-0046 was rationally designed to address treatment resistance that we believe may develop following the use of current investigational RET inhibitors as well as other multi-targeted approved RET inhibitors,” said Athena Countouriotis, M.D., president and chief executive officer. “Similar to our lead asset, repotrectinib, our preclinical work supports a potential role for TPX-0046 in both TKI-naïve and TKI-pretreated patients, and we look forward to initiating our Phase 1/2 study later this year. Clearing our second IND this year and advancing our third clinical drug candidate are major milestones for our company, as we seek to bring new therapies to market to address high unmet medical needs in difficult to treat cancers.”

Preclinical studies of TPX-0046 demonstrate potent inhibition of wildtype and mutated RET kinases as compared to proxy chemical compounds for investigational RET inhibitors, LOXO-292 and BLU-667. In cellular assays, TPX-0046 showed comparable potency against wildtype KIF5B-RET and stronger potency against the G810R solvent front mutation. These studies were presented on Sept. 28 at the 2019 congress of the European Society for Medical Oncology.

TPX-0046 is a multi-targeted RET and SRC kinase inhibitor with a novel three-dimensional macrocyclic structure. Activation of RET-- a receptor tyrosine kinase --through gain-of-function mutations and fusions has been found in multiple tumor types, including lung and thyroid cancers. Dual inhibitor of RET and SRC represents a novel therapeutic strategy to target abnormal RET signaling in cancers. Inhibition of SRC family kinases has the potential to reduce recruitment of multiple receptor tyrosine kinases involved in bypass resistance and therefore has the potential to increase the therapeutic effect of TPX-0046.

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 program, repotrectinib, is a next-generation kinase inhibitor targeting genetic drivers of non-small cell lung cancer and advanced solid tumors. Repotrectinib, which is currently being studied in a registrational Phase 2 study, has shown antitumor activity and durable responses among kinase inhibitor treatment-naïve and pre-treated patients. TPX-0022, Turning Point’s drug candidate targeting MET, CSF1R and SRC, is currently being studied in a Phase 1 trial of patients with advanced or metastatic solid tumors harboring oncogenic genetic alterations in MET. Turning Point’s 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 TPX-0046, the results, conduct and timing of Turning Point Therapeutics’ clinical trials, and plans regarding future clinical trials. 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, 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.

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