Turning Point Therapeutics Reports Third Quarter 2019 Financial and Operational Results

November 4, 2019

- ***Registrational Phase 2 Study of Repotrectinib Ongoing***
- ***Phase 1/2 Clinical Studies of RET/SRC Inhibitor TPX-0046 and Repotrectinib in Pediatric Patients On Track to Initiate in 2019***
- ***Mohammad Hirmand, M.D. Named Executive Vice President and Chief Medical Officer, Effective Dec. 2***
- ***Cash, Cash Equivalents, and Marketable Securities of $424 Million Expected to Fund Operations Beyond 2021***

SAN DIEGO, Nov. 04, 2019 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing novel drugs to address treatment resistance, today reported financial and operational highlights for the third quarter ended Sept. 30.

President and Chief Executive Officer Athena Countouriotis, M.D. said: “We achieved multiple important milestones during the third quarter, including with our lead drug candidate, repotrectinib, where we made progress in advancing our registrational Phase 2 study and reported another encouraging data update from the Phase 1 portion of our TRIDENT-1 study. We also made progress in our Phase 1 study of TPX-0022, a MET/CSF1R/SRC inhibitor and are on track to initiate very soon both our Phase 1/2 studies of TPX-0046, a RET/SRC inhibitor, and repotrectinib in pediatric patients.”

“Beyond this clinical progress, we raised net proceeds of $189.5 million in our follow-on stock offering to fund the company beyond 2021, and hired Dr. Mohmmad Hirmand as our chief medical officer. I am so happy to attract another senior leader of Mohammad’s caliber and look forward to working with him when he joins in early December.

“As I look ahead to the remainder of the year, we are focused on the execution of our ongoing clinical studies and the continued development of our pipeline, including our combination strategy with repotrectinib and selection of a candidate from our ALK program.”

Third quarter 2019 and recent highlights include:

- Continuing site activations and enrollment in the Phase 2 registrational portion of the TRIDENT-1 study of repotrectinib. The study is planned to be conducted at approximately 100 global sites with enrollment of approximately 310 patients, including *ROS1*-positive advanced non-small cell lung cancer (NSCLC) and *NTRK*-positive advanced solid tumor patients.
- Receiving FDA clearance at the end of September of the investigational new drug application for TPX-0046, a novel RET/SRC inhibitor, with an anticipated initiation of the Phase 1/2 clinical study in 2019. The open-label study is planned to enroll approximately 50 patients in the Phase 1 dose escalation portion and approximately 300 patients in the Phase 2 expansion portion to evaluate the safety profile and preliminary efficacy.
- Ongoing progress enrolling patients in the Phase 1 study of TPX-0022, Turning Point’s MET/CSF1R/SRC inhibitor. The study is designed to evaluate the overall safety, tolerability, pharmacokinetics (PK), and preliminary efficacy in a standard dose escalation design, followed by dose expansion once the recommended Phase 2 dose is determined. Total enrollment for both portions of the study is anticipated to be approximately 120 patients.
- Reporting and subsequently presenting at the European Society for Medical Oncology (ESMO) annual congress updated interim data from the Phase 1 portion of the TRIDENT-1 study of repotrectinib in *ROS1*-positive NSCLC patients. As of a July 22 data cut-off, the data showed a 91 percent confirmed overall response rate (cORR) in TKI-naive patients, a 39 percent cORR in patients treated with one prior TKI across all dose levels and a 55 percent cORR in patients treated with one prior TKI at the Phase 2 dose of 160 mg or above. Among patients treated with known solvent front mutations after crizotinib, the cORR was 43 percent. The safety profile remained consistent with prior updates, and 45 percent of *ROS*-positive NSCLC patients remained on treatment, including two for more than 24 months as of the data cut-off.
- Reporting and presenting at ESMO preclinical data for TPX-0046, demonstrating 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.
- Completing a follow-on public stock offering of 4.5 million shares of common stock, resulting in net proceeds of

$189.5 million.

- Appointing Mohammad Hirmand, M.D. as executive vice president and chief medical officer (CMO), effective Dec. 2. Dr. Hirmand has more than 20 years of biotechnology clinical development experience, most recently as CMO of Peloton Therapeutics, which was acquired by Merck in July. Prior to joining Peloton in 2017, Dr. Hirmand served as CMO of Medivation through its acquisition by Pfizer.

“Mohammad is a strategic leader with a strong background in oncology drug development, including early and late-stage clinical development and multiple drug approvals,” said Dr. Countouriotis. “He will be a valuable addition to our leadership team as we advance our three drug candidates in clinical studies, including our TRIDENT-1 global registrational study underway for repotrectinib.”

Third Quarter Financial Update
Operating expenses during the third quarter were $22.1 million compared to $6.1 million for the third quarter of 2018, and a sequential increase of $3.6 million from the second quarter. The $15.9 million year-over-year increase was primarily due to increased development spend for repotrectinib, TPX-0022 and TPX-0046 as well as personnel expenses that included $3.5 million in non-cash stock-based compensation.

For the nine months year-to-date, operating expenses totaled $54.5 million compared to $16.2 million during the prior-year period. The $38.5 million increase was driven by development expenses for repotrectinib, TPX-0022 and TPX-0046 and personnel expenses that included $8.5 million in non-cash stock-based compensation.

Net cash used in operating activities during the nine months ended Sept. 30 was $43.7 million.

Cash, cash equivalents and marketable securities at Sept. 30 totaled $423.6 million, an increase of $173.4 million from June 30 driven by proceeds from the September public stock offering. The company projects its cash position funds current operations beyond 2021.

Upcoming Milestones
Anticipated milestones for the remainder of 2019 include:

- Progress in site activations and patient enrollment in clinical studies of three drug candidates to advance the company’s wholly owned and internally discovered pipeline of kinase inhibitors;
- Initiation of a Phase 1/2 clinical study of TPX-0046 in patients with RET-altered NSCLC, thyroid cancer and other advanced solid tumors;
- Initiation of a Phase 1/2 clinical study of repotrectinib in pediatric patients with advanced ALK-, NTRK- and ROS1-positive tumors;
- Further advancement of the company’s pipeline with the nomination of a development candidate from a series of Turning Point designed ALK inhibitors;
- Advancing preclinical proof of concept for the company’s combination strategy for repotrectinib.

Webcast and Conference Call
Turning Point will webcast its Quarterly Update Conference Call today, Nov. 4 at 4:30 p.m. ET/1:30 p.m. PT. Dr. Countouriotis will host the call, which will be accessible live through the "Investors" section of tptherapeutics.com or by dialing (877) 388-2118 (in the United States) or (470) 495-9489 (outside the U.S.) using conference ID 8099367. A replay will be available through the "Investors" section of www.tptherapeutics.com.

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. The company’s pipeline of drug candidates also includes TPX-0022, targeting MET, CSF1R and SRC, which is currently being studied in a Phase 1 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in *MET*; and TPX-0046, targeting RET and SRC, which is planned for study in a Phase 1/2 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in *RET*. 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 Turning Point Therapeutics’ drug candidates, repotrectinib, TPX-0022 and TPX-0046, the results, conduct, progress and timing of Turning Point Therapeutics’ development programs and clinical trials including the TRIDENT-1 clinical study, the Phase 1 clinical study of TPX-0022 and the Phase1/2 clinical study of TPX-0046, plans regarding future clinical trials, the regulatory approval path for repotrectinib, the strength of Turning Point Therapeutics’ balance sheet and the adequacy of cash on hand. 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.

Turning Point Therapeutics, Inc.

Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 16,640	$ 5,129	$ 40,802	$ 13,841
General and administrative	5,500	1,000	13,857	2,319
Total operating expenses	22,140	6,129	54,659	16,160
Loss from operations	(22,140)	(6,129)	(54,659)	(16,160)
Interest income	1,657	132	3,487	393
Net loss	$ (20,483)	$ (5,997)	$ (51,172)	$ (15,767)
Other comprehensive income:				
Unrealized gain (loss) on marketable securities, net of tax	(24)	–	322	-
Comprehensive loss	$ (20,507)	$ (5,997)	$ (50,850)	$ (15,767)
Net loss per share, basic and diluted	$ (0.63)	$ (1.77)	$ (2.54)	$ (4.66)
Weighted-average common shares outstanding, basic and diluted	32,312,814	3,394,423	20,178,979	3,381,404

Turning Point Therapeutics, Inc.
Condensed Balance Sheets
(In thousands, except share amounts)

	September 30, 2019 (Unaudited)	**December 31, 2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 172,421	$ 101,029
Marketable securities	251,154	–
Prepaid expenses and other current assets	5,795	494
Total current assets	429,370	101,523
Property and equipment, net	2,184	1,000
Right-of-use assets from operating leases	4,761	–
Security deposits	73	73
Deferred financing costs	–	684
Total assets	$ 436,388	$ 103,280
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Liabilities:		
Current liabilities:		
Accounts payable	$ 3,811	$ 1,494
Accrued expenses and other current liabilities	2,950	2,415
Accrued compensation	3,784	1,413
Current portion of operating lease liabilities	1,175	–
Total current liabilities	11,720	5,322
Operating lease liabilities, net of current portion	4,144	448
Commitments and contingencies (Note 7)		
Convertible preferred stock	–	145,916

Total stockholders' equity (deficit)	420,524	(48,406)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 436,388	$ 103,280

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