Turning Point Therapeutics Reports Third-Quarter Financial Results, Provides Operational Updates

November 12, 2020

- ***Early Interim Data for TRIDENT-1 Phase 2 Study of Repotrectinib and Second Drug Candidate, TPX-0022, Recently Presented***
- ***Phase 2 TRIDENT-1 Registrational Study Full Site Activation and Timeline Update Anticipated in Early 2021***
- ***Four Clinical Studies of Three Drug Candidates Ongoing; Three Additional Clinical Studies Planned in 2021***
- ***Cash, Cash Equivalents, and Marketable Securities of $711 Million and Net Proceeds of Approximately $434 million from Recent Stock Offering Expected to Fund Current Operations into 2024***

SAN DIEGO, Nov. 12, 2020 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing next-generation therapies that target genetic drivers of cancer, today reported financial results and operational updates for the third quarter ended Sept. 30.

“We made substantial progress in our repotrectinib and TPX-0022 programs since our last quarterly update -- reporting early interim data from both the Phase 2 TRIDENT-1 registrational study of repotrectinib and the Phase 1 SHIELD-1 study of TPX-0022 – and raised net proceeds of approximately $434 million through our October stock offering to fund current operations into 2024,” said Athena Countouriotis, M.D., president and chief executive officer. “In addition, we continued to build a strong team to advance our pipeline of four drug candidates, with three new clinical trials planned for 2021, and importantly, to invest in earlier stage discovery. We look forward to completing our site activations in TRIDENT-1 and submitting our fourth IND in early 2021.”

Third quarter and recent highlights include:

- Progress in the Phase 2 TRIDENT-1 registrational study of repotrectinib, where the company reported early interim data in August. Utilizing a July 10, 2020 data cutoff, the preliminary efficacy and safety in the first 39 treated patients across multiple Phase 2 cohorts demonstrated confirmed objective response rates (ORR) of 86 percent in TKI-naïve ROS1-positive non-small cell lung cancer (NSCLC) patients (EXP-1: n=7); 40 percent in ROS1-positive NSCLC patients previously treated with a TKI and prior platinum-based chemotherapy (EXP2: n=5); 67 percent in ROS1-positive NSCLC patients previously treated with a TKI and no prior chemotherapy (EXP-4: n=6); and 50 percent in NTRK-positive TKI-pretreated patients (EXP-6: n=6), all by physician assessment. Repotrectinib was generally well tolerated, with the majority of treatment emergent adverse events reported as Grade 1 or 2.

  Turning Point has been granted three Fast Track designations by the Food and Drug Administration (FDA), in ROS1-positive advanced NSCLC patients who are 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.

  The company’s goal is to complete global activation of sites in the TRIDENT-1 study in early 2021, after which it plans to provide an update on the overall study timeline. Turning Point’s regional partner, Zai Lab, will continue to activate sites in 2021.

- Progress in the Phase 1 SHIELD-1 study of TPX-0022, Turning Point’s MET, SRC and CSF1R inhibitor, where initial data reported in a late-breaker oral presentation at the EORTC-NCI-AACR symposium highlighted preliminary clinical activity, including objective responses across multiple tumor types and a generally tolerable safety profile.

  The company anticipates initiating Phase 1 dose expansion after determining the recommended Phase 2 dose. The company also plans to discuss the ongoing Phase 1 SHIELD-1 study with the FDA to potentially modify the trial into a registrational Phase 1/2 design with the goal to initiate the Phase 2 portion of the study in the second half of 2021, pending FDA feedback.

- Two additional trials ongoing, including the Phase 1/2 open-label study to assess repotrectinib in pediatric patients with ALK-, NTRK- or ROS1-positive advanced solid tumors; and the Phase 1/2 study of RET-inhibitor TPX-0046.

- Presenting preclinical data in a *KRAS* G12C NSCLC tumor xenograft model demonstrating repotrectinib significantly enhanced the efficacy of AMG-510 and showed a marked survival benefit when compared to AMG-510 alone. Repotrectinib has previously demonstrated synergy in preclinical models with AMG-510 and a MEK inhibitor. Based on these preclinical data, Turning Point plans to initiate a clinical combination study in KRAS mutant NSCLC in mid-2021.

- Completing a follow-on public stock offering generating net proceeds to Turning Point of approximately $434 million.

Third Quarter Financial Update
Revenue of $25 million recorded in the quarter was the result of an upfront payment from Zai Lab under the company's license agreement for repotrectinib in Greater China. Operating expenses for the third quarter totaled $43.5 million compared to $22.1 million in the third quarter of 2019. Primary drivers of the year-over-year increase were investments made to develop repotrectinib, TPX-0022, TPX-0046 and personnel expenses.

Excluding a one-time non-cash stock-based compensation charge in the first quarter, non-GAAP operating expenses for the first nine months totaled $107.5 million compared to $54.7 million in the prior-year period. Year-to-date net cash used in operating activities was $49.4 million.

Cash, cash equivalents and marketable securities at Sept. 30 totaled $711.4 million, an increase of $1 million from June 30 driven by the upfront payment from Zai Lab, partially offset by cash used in operating activities for the quarter. In addition, Turning Point completed a follow-on public stock offering in October that generated net proceeds of $433.6 million. Turning Point Therapeutics projects its cash position funds current operations into 2024.

Upcoming Milestones
Key milestones anticipated into 2021 include:

- TRIDENT-1 data presentation in a mini-oral session at the World Conference on Lung Cancer in January 2021.

- Achievement of full TRIDENT-1 global site activation in early 2021, excluding sites within China managed by the company's partner Zai Lab, and an update on the overall study timeline in early 2021.

- Submitting an investigational new drug application to the FDA for ALK-inhibitor TPX-0131 in early 2021.

- Reporting early interim data from initial patients in the Phase 1 study of RET-inhibitor TPX-0046 in the first half of 2021.

- Initiation of TRIDENT-2, a planned Phase 2 combination study of repotrectinib in patients with *KRAS* mutant NSCLC in mid-2021.

- Initiation of the planned Phase 2 portion of the SHIELD-1 study of TPX-0022 in the second half of 2021, pending FDA feedback.

- Initiation of SHIELD-2, a planned Phase 2 study of TPX-0022 in combination with an inhibitor of epidermal growth factor receptor (EGFR), in the second half of 2021.

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 called TRIDENT-1 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 in a Phase 1 study called SHIELD-1 in patients with advanced or metastatic solid tumors harboring genetic alterations in *MET*; RET-inhibitor TPX-0046, which is in a Phase 1/2 study of patients with advanced or metastatic solid tumors harboring genetic alterations in *RET*; and ALK-inhibitor TPX-0131, which is in IND-enabling studies. 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.

Non-GAAP Financial Measures
In addition to the financial results that are provided in accordance with accounting principles generally accepted in the United States (GAAP), this press release also contains a non-GAAP financial measure. When preparing our supplemental non-GAAP financial results, the Company excluded certain GAAP items that management does not consider to be normal. In particular, the non-GAAP measure excludes non-cash stock-based compensation expense relating to a one-time charge of $31.4 million associated with previously disclosed modifications to the vesting of existing stock options, pursuant to the transition agreement with the company's scientific founder. This non-GAAP measure is provided as a complement to results provided in accordance with GAAP as management believes this non-GAAP financial measure is important in comparing current results with prior-period results. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the attached financial information.

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, TPX-0046 and TPX-0131, the results,

conduct, progress and timing of Turning Point Therapeutics' development programs and clinical trials including the Phase 2 TRIDENT-1 clinical study, the Phase 1/2 pediatric clinical study of repotrectinib, the Phase 1 SHIELD-1 clinical study of TPX-0022 and the Phase 1/2 clinical study of TPX-0046, plans regarding future clinical trials and regulatory submissions, the regulatory approval path for repotrectinib, the potential to receive milestone and royalty payments from Zai Lab, 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, 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. 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.
Balance Sheet Data
(In thousands)
(unaudited)

	September 30, 2020	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$ 711,388	$ 409,151
Working capital	697,907	400,915
Total assets	724,633	422,202
Accumulated deficit	(232,800)	(122,884)
Total stockholders' equity	701,588	404,351

TURNING POINT THERAPEUTICS, INC.
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,	
	2020	2019	2020	2019
Revenue	$ 25,000	-	$ 25,000	$ -
Operating expenses:				
Research and development	32,213	16,640	79,136	40,802
General and administrative	11,326	5,500	59,761	13,857
Total operating expenses	43,539	22,140	138,897	54,659
Loss from operations	(18,539)	(22,140)	(113,897)	(54,659)
Other income, net	834	1,657	3,981	3,487
Net loss	(17,705)	(20,483)	(109,916)	(51,172)
Unrealized gain / (loss) on marketable securities, net of tax	(606)	(24)	141	322
Comprehensive loss	$ (18,311)	$ (20,507)	$ (109,775)	$ (50,850)
Net loss per share, basic and diluted	$ (0.42)	$ (0.63)	$ (2.82)	$ (2.54)
Weighted-average common shares outstanding, basic and diluted	42,185,824	32,312,814	38,914,789	20,178,979

TURNING POINT THERAPEUTICS, INC.
Reconciliation of GAAP to Non-GAAP Financial Results
(In thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
GAAP Operating Expenses	$ (43,539)	$ (22,140)	$ (138,897)	$ (54,659)
Adjustments:				
Share-based compensation expense (1)	–	–	31,405	–
Non-GAAP Operating Expenses	$ (43,539)	$ (22,140)	$ (107,492)	$ (54,659)

(1) During the first quarter of 2020, the Company recognized in non-cash stock-based compensation expense a one-time charge of $31.4 million

associated with previously disclosed modifications to the vesting of existing stock options, pursuant to the transition agreement with the company's scientific founder.

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Source: Turning Point Therapeutics, Inc.