Turning Point Therapeutics Reports Second Quarter 2019 Financial and Operational Results

August 6, 2019

- ***FDA Accepts Repotrectinib Recommended Phase 2 Dose Regimen for Registrational TRIDENT-1 Study***
- ***Two Abstracts Selected for Presentation at the European Society for Medical Oncology (ESMO) Annual Congress Highlighting Clinical Data for Repotrectinib in ROS1 and TRK patients, and Preclinical Data for RET/SRC Inhibitor TPX-0046***
- ***Phase 1 Study Initiated for Drug Candidate TPX-0022, a Novel MET/CSF1R/SRC Inhibitor***
- ***Yi Larson Hired as Executive Vice President, Chief Financial Officer***
- ***Cash, Cash Equivalents, and Marketable Securities of $250 Million Funds Operations into the Second Half of 2021***

SAN DIEGO, Aug. 06, 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 second quarter ended June 30.

“During the second quarter of 2019 – our first quarter as a public company – we achieved a number of key milestones, including a successful public stock offering, our first oral presentation at ASCO of Phase 1 data from lead drug candidate repotrectinib, initiation of our Phase 2 registrational study, and initiation of the Phase 1 clinical study of our novel MET/CSF1R/SRC inhibitor, TPX-0022, following clearance of the IND,” said Athena Countouriotis, M.D, president and chief executive officer.

“Looking ahead to the second half of the year, I am very pleased to have Yi Larson join us as our first chief financial officer as we execute our plans to further expand clinical development and advance the pipeline. Our goals for the second half include activating global sites and enrolling patients in our TRIDENT-1 registrational study; submitting the IND for TPX-0046, our novel RET/SRC inhibitor; presenting updated Phase 1 clinical data from our ongoing TRIDENT-1 study and new preclinical data from TPX-0046 at ESMO; and initiating two additional clinical studies.”

The U.S. Food and Drug Administration (FDA) recently accepted the company’s recommended Phase 2 dose regimen for repotrectinib in the registrational TRIDENT-1 study. The regimen will dose patients at 160 mg daily for the first 14 days, after which the dose may be increased to 160 mg twice daily based on patient tolerability.

The Phase 2 portion of the TRIDENT-1 study was initiated in June and will be conducted at approximately 100 global sites with planned enrollment of approximately 310 ROS1-positive and NTRK-positive non-small cell lung cancer (NSCLC) and other solid tumor patients.

Other second quarter 2019 and recent highlights include:

- Oral presentation of positive interim data from the Phase 1 portion of the TRIDENT-1 study at the American Society of Clinical Oncology (ASCO) Annual Meeting. Among the findings as of a March 4 data cut-off, data by blinded independent central review (BICR) with more than 16 months of median follow up showed in TKI-naïve ROS1+ patients a confirmed overall response rate (ORR) of 82 percent across seven dose levels, and 83 percent at a dose of 160 mg and above. The median duration of response was not yet met. In addition, confirmed ORR by BICR in ROS1+ patients pretreated with one prior TKI was 39 percent across seven dose levels and 55 percent at 160 mg and above. In patients with a documented G2032R solvent front mutation, the confirmed ORR was 40 percent. The overall safety profile showed repotrectinib continued to be generally well tolerated, with 45 percent of patients (n=15 of 33) remaining on treatment and 12 of the 15 patients remaining on repotrectinib for greater than 12 months as of the data cut-off.

- Presentation of four preclinical studies at the American Association for Cancer Research (AACR) Annual Conference, including two studies highlighting the preclinical potency of repotrectinib and two studies highlighting the ability of TPX-0022, the company’s investigational MET/CSF1R/SRC inhibitor, to potently inhibit *MET*-driven cancer cells, modulate the tumor microenvironment and demonstrate tumor regression and tumor growth inhibition.

- Initiation of a Phase 1 first-in-human, open-label clinical study of TPX-0022 for patients with advanced solid tumors harboring genetic alterations in *MET* following FDA clearance of the investigational new drug (IND) application.

- FDA approval of an investigational device exemption (IDE) for the diagnostic assay being used in the registrational Phase 2 portion of TRIDENT-1 study of repotrectinib. The assay is intended to identify patients with ROS1, NTRK1-3 or ALK gene fusions in advanced solid tumors.

- Completion of the company's initial public stock offering at $18 per share, raising net proceeds of $175 million.
- The appointment of Yi Larson as executive vice president and chief financial officer, who will join the company on August 26 from Goldman Sachs & Co. where she most recently served as a managing director in Healthcare Investment Banking.
- The addition of Patrick Machado, J.D., and Carol Gallagher, Pharm.D., both 20+ year biotech leaders to the company's board of directors.

Second Quarter Financial Update
Operating expenses during the second quarter were $18.5 million compared to $14.1 million in the first quarter and $5.2 million in the second quarter of 2018. The $13.3 million year-over-year increase was primarily due to increased development spend for repotrectinib, TPX-0022 and TPX-0046 as well as personnel expenses. Net cash used in operating activities during the quarter was $16.9 million, bringing year-to-date net cash used in operating activities to $27.1 million.

Turning Point expects expenses will increase through the year as it activates sites for its Phase 2 study of repotrectinib and Phase 1 study of TPX-0022. In addition, the company plans to initiate up to two additional clinical trials in 2019, including the Phase 1/2 study of repotrectinib in pediatric and young adult patients with advanced solid tumors with *NTRK, ALK*, or *ROS1* alterations and, pending submission and subsequent IND clearance, a Phase 1 study of TPX-0046 in patients with advanced solid tumors with oncogenic RET genetic alterations.

Cash, cash equivalents and marketable securities at June 30 totaled $250.2 million, an increase from $90 million at March 31 driven by proceeds from its April 2019 initial public offering. The company projects its cash position funds current operations into the second half of 2021.

Upcoming Milestones
Anticipated milestones for the second half of 2019, include:

- Submission of an IND for TPX-0046, and pending IND clearance, initiation of the Phase 1 clinical study.
- Presentation at ESMO of an update from the ongoing TRIDENT-1 Phase 1 study of repotrectinib, which will include additional follow-up since the last data cut-off and a limited number of new patients.
- Presentation at ESMO of preclinical data for Turning Point's pre-IND novel RET/SRC inhibitor TPX-0046. The presentation will build on prior preclinical work against proxy molecules with new preclinical potency data.
- Initiation of a Phase 1 clinical study of repotrectinib in pediatric and young adult patients with advanced solid tumors with NTRK, ALK, or ROS1 alterations.
- Nomination of a development candidate from a series of Turning Point designed ALK inhibitors.

Webcast and Conference Call
Turning Point will webcast its Quarterly Update Conference Call today, Aug. 6 at 4:30 p.m. ET/1:30 p.m. PT. Dr. Countouriotis will host the call, which will be webcast 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 8889554. 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. 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 Phase 1/2 TRIDENT-1 clinical study and the Phase 1 clinical study of TPX-0022, 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.

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

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 78,781	$ 101,029
Marketable securities, available for sale	171,389	–
Prepaid expenses and other current assets	4,998	494
Total current assets	255,168	101,523
Property and equipment, net	954	1,000
Right-of-use assets from operating leases	1,250	–
Security deposits	73	73
Deferred financing costs	–	684
Total assets	$ 257,445	$ 103,280
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Liabilities:		
Current liabilities:		
Accounts payable	$ 4,086	$ 1,494
Accrued expenses and other current liabilities	1,992	2,415
Accrued compensation	1,672	1,413
Current portion of operating lease liabilities	138	–
Total current liabilities	7,888	5,322
Other long-term liabilities	260	–
Operating lease liabilities, net of current portion	1,382	448
Commitments and contingencies		
Convertible preferred stock, $0.0001 par value; 0 shares issued and outstanding as of June 30, 2019 and 65,423,901 shares issued and outstanding as of December 31, 2018; aggregate liquidation preference of $0 and $146,460 as of June 30, 2019 and December 31, 2018, respectively	–	145,916
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 200,000,000 shares authorized as of June 30, 2019 and 104,000,000 shares authorized as of December 31, 2018; 31,297,423 shares issued and outstanding as of June 30, 2019; 3,411,516 shares issued and outstanding at December 31, 2018	34	1
Additional paid-in capital	328,978	2,346
Accumulated other comprehensive income	345	–
Accumulated deficit	(81,442)	(50,753)
Total stockholders' equity (deficit)	247,915	(48,406)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 257,445	$ 103,280

Turning Point Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 13,711	$ 4,369	$ 24,162	$ 8,713
General and administrative	4,743	803	8,357	1,319
Total operating expenses	18,454	5,172	32,519	10,032
Loss from operations	(18,454)	(5,172)	(32,519)	(10,032)
Interest income	1,312	135	1,830	262
Net loss	$ (17,142)	$ (5,037)	$ (30,689)	$ (9,770)
Other comprehensive income:				
Unrealized gain on marketable securities, net of tax	345	–	345	–
Comprehensive loss	$ (16,797)	$ (5,037)	$ (30,344)	$ (9,770)
Net loss per share, basic and diluted	$ (0.70)	$ (1.49)	$ (2.19)	$ (2.89)
Weighted-average common shares outstanding, basic and diluted	24,479,767	3,380,899	14,004,957	3,374,787

Source: Turning Point Therapeutics, Inc.