Turning Point Therapeutics Reports Fourth-Quarter and Full-Year Financial Results, Provides Operational Updates

March 1, 2021

- ***Continued Strong Enrollment in TRIDENT-1 Registrational Study, with Phase 1/2 Enrollment in EXP-1 Expected to Reach 50 Patients in 2Q; Type B Meeting with FDA Planned in 2Q***
- ***TPX-0131 Phase 1/2 Study Approved by Australian Ethics Committee; IND Submission Planned in March with Study Activation Anticipated in 2Q***
- ***Multiple Pipeline Presentations Planned at Medical Conferences in 2Q***
- ***Cash, Cash Equivalents, and Marketable Securities of $1.1 Billion Expected to Fund Current Operations into 2024***

SAN DIEGO, March 01, 2021 (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 fourth quarter and year ended Dec. 31, 2020.

“The progress we made during the fourth quarter and in 2020 has set us up for another potentially pivotal year in 2021, with multiple anticipated milestones across our portfolio,” said Athena Countouriotis, M.D., president and CEO. “Our growing team continues to execute well as we advance our pipeline of precision oncology drug candidates.”

Fourth quarter 2020 and recent highlights include:

REPOTRECTINIB, ROS1/TRK Inhibitor

- Progress in the Phase 2 TRIDENT-1 registrational study of lead drug candidate repotrectinib, where the company in January reported updated interim findings in patients with ROS1-positive TKI-naïve non-small cell lung cancer (NSCLC). As of the Dec. 31, 2020 data cutoff date in 15 patients enrolled in the Phase 2 portion of the TRIDENT-1 study, the preliminary efficacy analysis showed a confirmed objective response rate (ORR) by physician assessment of 93% (95% CI: 68-100), and in 22 patients pooled from the Phase 1 (dosed at or above the Phase 2 dose) and Phase 2 portions, the confirmed ORR was 91% (95% CI: 71-99). As of an Oct. 30, 2020 data cutoff date, the interim safety update in a total of 185 patients from the Phase 1 and Phase 2 portions of the study showed repotrectinib was generally well tolerated.
- Strong enrollment in the TRIDENT-1 study during the fourth quarter and into 2021, with Turning Point now anticipating enrollment in cohort 1 (EXP-1) to reach 50 patients pooled from the Phase 1 and Phase 2 portions of the study in the second quarter of 2021. The company plans to discuss next steps towards registration of repotrectinib in this patient population at a Type B meeting with the Food and Drug Administration (FDA), also anticipated in the second quarter. In addition, enrollment in the other cohorts within TRIDENT-1 continues to progress, and it is the company’s goal to provide an enrollment and clinical data update for other cohorts in the study in the second half.
- Breakthrough Therapy Designation (BTD) granted by the FDA for the treatment of patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 tyrosine kinase inhibitor. BTD is granted by the FDA to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition.
- Plans to present additional preclinical data highlighting repotrectinib’s combination potential in KRAS-mutant disease at a medical conference in the second quarter of 2021.
- Progress toward initiating the first cohort in the multi-arm Phase 1b/2 TRIDENT-2 repotrectinib combination study in *KRAS*-mutant solid tumors in mid-2021.

TPX-0022, MET/ SRC/CSF1R Inhibitor

- Progress in the Phase 1 SHIELD-1 study of TPX-0022, Turning Point’s MET, SRC and CSF1R inhibitor, where initial data reported in October 2020 highlighted preliminary clinical activity, including objective responses across multiple tumor types and a generally well-tolerated safety profile.

The company continues to enroll patients in the Phase 1 study and is currently evaluating multiple doses and schedules to further characterize the pharmacokinetics, safety and efficacy profile before ultimately determining a recommended Phase 2 dose (RP2D), anticipated in the second quarter. Turning Point plans to proceed directly into Phase 1 dose expansion in multiple patient cohorts after determining RP2D.

- Additional clinical data update from the Phase 1 dose finding portion of SHIELD-1 planned in the second half of 2021. The company also plans to discuss the ongoing study with the FDA with the goal to modify the study into a registrational Phase 1/2 design and initiate the Phase 2 portion in the second half, pending FDA feedback.

- Execution of an agreement with Zai Lab in January 2021 to develop and commercialize TPX-0022 in Greater China.

TPX-0046, RET Inhibitor

- Progress in the Phase 1 dose finding study of TPX-0046, a novel RET inhibitor, where the company continues to evaluate multiple doses and schedules to further characterize the pharmacokinetics, safety, and efficacy profile. Turning Point plans to provide preliminary data in the second quarter of 2021, which will focus primarily on safety and any early signals of efficacy from initial patients.

TPX-0131, ALK Inhibitor

- Approval by the Australian Ethics Committee of the Phase 1/2 clinical study of TPX-0131 focused on ALK-positive TKI-pretreated advanced NSCLC patients. Study initiation is anticipated in the second quarter of 2021.

- IND submission to the FDA on track for March for TPX-0131, Turning Point's fourth drug candidate, which has a compact macrocyclic structure that has been shown in preclinical studies to potently inhibit wildtype ALK and numerous ALK mutations, and in in-vivo studies has shown significant brain tissue penetration after repeat oral dosing supporting the potential to cross the blood-brain barrier.

- Presentation of additional preclinical data highlighting the profile of TPX-0131 at a medical conference in the second quarter of 2021.

Fourth Quarter and Full-Year 2020 Financial Results

- Revenue: Revenue of $25 million for the year was recognized during the third quarter in connection with the upfront payment from Zai Lab under the company's license agreement for repotrectinib in Greater China.

- R&D Expenses: Research and development expenses were $34.3 million for the fourth quarter compared to $17.1 million for the fourth quarter of 2019, and $113.4 million for the year compared to $57.9 million for the year ended Dec. 31, 2019. Primary drivers of the year-over-year increase were investments made to develop repotrectinib, TPX-0022, TPX-0046, TPX-0131, discovery efforts and personnel expenses.

- G&A Expenses: General and administrative expenses were $13.7 million for the fourth quarter compared to $5.9 million for the fourth quarter of 2019, and excluding a one-time non-cash stock-based compensation charge from the first quarter, non-GAAP G&A expenses were $42 million for the year compared to $19.8 million for the year ended Dec. 31, 2019. The increase was primarily attributable to higher personnel expenses as a result of increased employee head count and professional fees for legal and accounting services.

- Net Income/Loss: Net loss was $47.4 million for the fourth quarter compared to net loss of $21 million for the fourth quarter of 2019, and excluding a one-time non-cash stock-based compensation charge from the first quarter, non-GAAP net loss was $125.9 million for the year compared to a loss of $72.1 million for the year ended Dec. 31, 2019.

- Cash position: Cash, cash equivalents and marketable securities at Dec. 31 totaled $1.1 billion, compared to $409.2 million as of Dec. 31, 2019, driven primarily by net proceeds from follow-on public stock offerings in May and October of $351.6 and $433.9 million, respectively, partially offset by cash used in operating activities. Net cash used in operating activities during 2020 was $82.8 million. Turning Point projects its cash position funds current operations into 2024.

Upcoming Milestones
Key milestones anticipated in 2021 include:

Repotrectinib

- Reach enrollment of 50 patients pooled from the Phase 1 and Phase 2 portions of the TRIDENT-1 study in the

ROS1-positive TKI-naïve NSCLC patient cohort (EXP-1) in second quarter

- Discuss next steps towards registration of repotrectinib in patients with ROS1-positive TKI-naïve NSCLC at a Type B meeting with the FDA in the second quarter
- Initiate the first cohort of a multi-arm Phase 1b/2 TRIDENT-2 combination study in patients with *KRAS*-mutant solid tumors mid-year
- Provide an enrollment and clinical data update in other cohorts of the Phase 2 TRIDENT-1 study in the second half

TPX-0046

- Report early interim data from initial patients enrolled in the dose finding portion of the TPX-0046 Phase 1 study in the second quarter

TPX-0022

- Provide a clinical data update from the Phase 1 dose finding portion of the SHIELD-1 study in the second half
- Initiate the Phase 2 portion of the SHIELD-1 study of TPX-0022, pending FDA feedback, in the second half
- Initiate the Phase 1b/2 SHIELD-2 study of TPX-0022 in combination with an epidermal growth factor receptor (EGFR) targeted therapy in the second half

TPX-0131

- Submit the IND for TPX-0131 in the first quarter
- Initiate the Phase 1/2 clinical study of TPX-0131 focused on ALK-positive TKI-pretreated advanced NSCLC patients in the second quarter

Preclinical/Research

- Present multiple preclinical data presentations in the second quarter
- Outline research strategy in the second half, including focus and anticipated timeline to development candidates.

Webcast and Conference Call
Turning Point will webcast its Quarterly Update Conference Call today, March 1 at 4:30 p.m. ET/1:30 p.m. PT. Dr. Countouriotis will host the call, which will be accessible 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 5683087. 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 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 currently pending IND submission. 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 non-GAAP financial measures. 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 measures exclude 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. These non-GAAP measures are provided as a complement to results provided in accordance with GAAP as management believes these non-GAAP financial measures are 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' research and development programs and clinical trials, including the TRIDENT-1 clinical study of repotrectinib, the SHIELD-1 clinical study of TPX-0022 and the Phase 1/2 clinical study of TPX-0046, plans regarding future data presentations, clinical trials and regulatory submissions, the regulatory approval path for repotrectinib, and 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)

	December 31, 2020	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$ 1,122,508	$ 409,151
Working capital	1,106,287	400,915
Total assets	1,136,713	422,202
Accumulated deficit	(280,176)	(122,884)
Total stockholders' equity	$ 1,109,898	$ 404,351

TURNING POINT THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(**unaudited**)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenue	$ -	-	$ 25,000	$ -
Operating expenses:				
Research and development	34,275	17,141	113,411	57,943
General and administrative	13,664	5,924	73,425	19,781
Total operating expenses	47,939	23,065	186,836	77,724
Loss from operations	(47,939)	(23,065)	(161,836)	(77,724)
Other income, net	563	2,106	4,544	5,593
Net loss	(47,376)	(20,959)	(157,292)	(72,131)
Unrealized gain (loss) on marketable securities, net of tax	(203)	(50)	(62)	271
Comprehensive loss	$ (47,579)	$ (21,009)	$ (157,354)	$ (71,860)
Net loss per share, basic and diluted	$ (1.02)	$ (0.58)	$ (3.85)	$ (2.99)
Weighted-average common shares outstanding, basic and diluted	46,588,835	35,851,252	40,843,782	24,124,924

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
GAAP Net Loss	$ (47,376)	$ (20,959)	$ (157,292)	$ (72,131)
Adjustments:				
Share-based compensation expense (1)	–	–	31,405	–
Non-GAAP Net Loss	$ (47,376)	$ (20,959)	$ (125,887)	$ (72,131)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
GAAP General & Administrative Expenses	$ (13,664)	$ (5,924)	$ (73,425)	$ (19,781)
Adjustments:				
Share-based compensation expense (1)	–	–	31,405	–
Non-GAAP General & Administrative Expenses	$ (13,664)	$ (5,924)	$ (42,020)	$ (19,781)

(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.