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

May 5, 2021

- ***FDA Type B Meeting Feedback Supports Discussion of Topline BICR Results for Repotrectinib in TKI-Naïve ROS1+ NSCLC Patients After 6 Months or Greater Follow-up; FDA Meeting Anticipated in 1Q 2022***
- ***Investigational New Drug Application Cleared for Combination of Repotrectinib and MEK-inhibitor Trametinib in KRAS-Driven Tumors; TRIDENT-2 Study on Track to Initiate Mid-Year***
- ***TPX-0022 SHIELD-1 Study Progressing Toward Recommended Phase 2 Dose***
- ***TPX-0131 Phase 1/2 FORGE-1 Study Initiated***
- ***Cash, Cash Equivalents, and Marketable Securities of $1.1 Billion Expected to Fund Current Operations into 2024***

SAN DIEGO, May 05, 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 first quarter ended March 31, 2021.

“Our team continues to execute well and has achieved multiple key milestones, including completing a Type B meeting with the FDA for our lead drug candidate, repotrectinib, as well as clearing our fourth IND and initiating our fourth clinical study in less than 2 years,” said Athena Countouriotis, M.D., president and CEO. “We are pleased with the feedback from the Type B meeting and look forward to the discussion with the FDA about the topline results from patients treated within cohort 1 of our TRIDENT-1 study, which we anticipate in the first quarter of next year.”

First quarter and recent highlights include:

REPOTRECTINIB, ROS1/TRK Inhibitor

- Completion of a Type B meeting with the Food and Drug Administration (FDA) to discuss potential next steps for repotrectinib in patients treated within cohort 1 (EXP-1) of the registrational TRIDENT-1 study. The FDA guided that a meeting should be requested to discuss topline blinded independent central review (BICR) results when responders have been followed for at least six months past onset of response. Turning Point believes it may be in a position to discuss the topline results from patients treated within EXP-1 with the FDA during the first quarter of 2022.
- Clearance of an investigational new drug (IND) application for the combination of repotrectinib and MEK-inhibitor trametinib in KRAS-driven tumors. The company anticipates the first cohort of its planned Phase 1b/2 TRIDENT-2 study will examine the safety, tolerability, pharmacokinetics, and any early signals of efficacy of repotrectinib in combination with trametinib in patients with *KRAS* mutant *G12D* advanced solid tumors. The study is planned for initiation in mid-2021.
- Presentation of preclinical data at the American Association for Cancer Research (AACR) annual meeting demonstrating that repotrectinib in combination with trametinib was more effective than single-agent treatment of either repotrectinib or trametinib in patient-derived KRAS mutant G12D/V lung and G12D/V/R pancreatic cancer models.

  In earlier preclinical studies, repotrectinib’s inhibition of SRC, FAK and JAK2 at therapeutically relevant concentrations in combination with trametinib demonstrated a synergistic effect over either single agent by reducing tumor cell growth and enhancing tumor cell death in a *KRAS* mutant G12D lung cancer model.
- Progress in the ongoing Phase 1/2 CARE study in pediatric and young adult patients with advanced solid tumors harboring ALK, ROS1 or NTRK alterations. The company plans to report initial data from the study in the second half of 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 the company continues to enroll patients and evaluate multiple doses and schedules to further characterize the pharmacokinetics, safety and efficacy profile before determining a recommended Phase 2 dose (RP2D), anticipated in the second quarter of 2021. Turning Point plans to proceed directly into multiple Phase 1 dose expansion cohorts after determining the RP2D and to prepare for an end of Phase 1 meeting in the second half of 2021.

- Presentation of preclinical data at AACR demonstrating potential utility of TPX-0022 in combination with immune checkpoint inhibitors. In a syngeneic xenograft tumor model, TPX-0022 downregulated immunosuppressive cytokines, increased anti-tumor M1 macrophages, and enriched levels of CD8-positive cytotoxic T cells. TPX-0022 had single agent in vivo efficacy and enhanced the efficacy of an anti-PD-1 inhibitor. The company is evaluating a clinical combination study of TPX-0022 and an anti-PD-1 checkpoint inhibitor.

TPX-0046, RET Inhibitor

- Reporting initial data from the Phase 1 dose finding portion of the Phase 1/2 SWORD-1 study, which showed preliminary clinical activity, including objective responses and a generally well-tolerated safety profile in patients with RET-positive non-small cell lung cancer (NSCLC) and medullary thyroid carcinoma.

- Progress in the ongoing dose-finding portion of the study, where the company continues to evaluate multiple doses and schedules to further characterize the pharmacokinetics, safety, and efficacy profile before determining the RP2D. The company has revised the study protocol to include multiple Phase 1 dose expansion cohorts following determination of the RP2D.

TPX-0131, ALK Inhibitor

- Clearance of the IND for TPX-0131, the company'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 brain tissue penetration after repeat oral dosing.

- Initiation of the Phase 1/2 FORGE-1 study of TPX-0131 in patients with locally advanced or metastatic TKI-pretreated ALK-positive NSCLC. The study endpoints include safety and tolerability, determination of the maximum tolerated dose and/or the recommended Phase 2 dose, and objective response rate by RECIST 1.1.

- Presentation of preclinical data at AACR demonstrating the potential for TPX-0131 to cross the blood-brain barrier in vivo, and potency against wild type ALK (IC_{50}=0.4 nM) and a broad spectrum of acquired ALK resistance mutations, including the G1202R solvent front mutation (IC_{50}=0.2 nM), L1196M gatekeeper mutation (IC_{50}=0.5 nM), and multiple compound mutations (IC_{50}< 1 nM) based on cell proliferation assays.

First Quarter Financial Results

- Revenue: Revenue of $25.2 million recognized during the quarter included a $25 million upfront payment from Zai Lab (Shanghai) Co. Ltd., under the company's license agreement for TPX-0022 in Greater China, and $0.2 million from clinical drug supply to Zai Lab under the company's repotrectinib license agreement.

- R&D Expenses: Research and development expenses were $41.3 million in the quarter, compared to $22.8 million in the first quarter of 2020. The $18.5 million increase was primarily driven by the year-over-year increase in investments to develop repotrectinib, TPX-0022, TPX-0046 and TPX-0131, discovery efforts and personnel expenses.

- G&A Expenses: General and administrative expenses were $20 million compared to $39.9 million in the first quarter of 2020. Excluding a one-time non-cash stock-based compensation charge from the first quarter of 2020, non-GAAP G&A expenses increased by $11.5 million, primarily related to higher personnel expenses from an increase in head count and professional services.

- Net Income/Loss: Net loss was $35.5 million compared to a net loss of $60.7 million for the first quarter of 2020, and excluding the one-time non-cash stock-based compensation charge from the first quarter of 2020, non-GAAP net loss increased by $6.2 million.

- Cash position: Cash, cash equivalents and marketable securities at March 31, 2021 totaled $1.1 billion, compared to $1.1 billion as of Dec. 31, 2020, driven primarily by $25.2 million in revenue, partially offset by cash used in operating activities. Net cash used in operating activities during the first quarter was $15.7 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

- Initiate the first cohort of a multi-arm Phase 1b/2 TRIDENT-2 combination study in patients with *KRAS* mutant *G12D* advanced solid tumors mid-year
- Provide an enrollment and clinical data update from the Phase 2 TRIDENT-1 study in the second half
- Report initial clinical data from the ongoing Phase 1/2 CARE study in pediatric and young adult patients in the second half

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

Preclinical/Research

- Outline research strategy in the second half, including anticipated timeline to development candidates.

Webcast and Conference Call
Turning Point will webcast its Quarterly Update Conference Call today, May 5 at 5:00 p.m. ET/2:00 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 7397513. 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, which is being studied in a Phase 1/2 trial of previously treated patients with ALK-positive advanced or metastatic non-small cell lung cancer. 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, plans regarding future data presentations, clinical trials, regulatory meetings 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.

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TURNING POINT THERAPEUTICS, INC.
Balance Sheet Data
(In thousands)
(unaudited)

	March 31, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$ 1,114,777	$ 1,122,508
Working capital	1,097,541	1,106,287
Total assets	1,127,584	1,136,713
Accumulated deficit	(315,680)	(280,176)
Total stockholders' equity	$ 1,101,165	$ 1,109,898

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue	$ 25,205	-
Operating expenses:		
Research and development	41,263	22,769
General and administrative	19,991	39,857
Total operating expenses	61,254	62,626
Loss from operations	(36,049)	(62,626)
Other income, net	545	1,908
Net loss	(35,504)	(60,718)
Unrealized loss on marketable securities	(186)	(316)
Comprehensive loss	$ (35,690)	$ (61,034)
Net loss per share, basic and diluted	$ (0.73)	$ (1.69)
Weighted-average common shares outstanding, basic and diluted	48,920,403	35,919,358

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

	Three Months Ended March 31,	
	2021	**2020**
GAAP Net Loss	$ (35,504)	$ (60,718)
Adjustments:		
Share-based compensation expense (1)	–	31,405
Non-GAAP Net Loss	$ (35,504)	$ (29,313)

	Three Months Ended March 31,	
	2021	**2020**
GAAP General & Administrative	$ (19,991)	$ (39,857)
Adjustments:		
Share-based compensation expense (1)	–	31,405
Non-GAAP General & Administrative	$ (19,991)	$ (8,452)

(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.

Source: Turning Point Therapeutics, Inc.