Turning Point Therapeutics Reports Second-Quarter 2022 Financial Results, Provides Operational Updates

August 8, 2022

- ***Positive feedback from pre-new drug application (NDA) meeting with U.S. Food and Drug Administration (FDA) focused on TRIDENT-1 registrational study of repotrectinib***
- ***Initiated the Phase 1b/2 SHIELD-2 combination study of elzovantinib and aumolertinib in EGFR mutant MET-amplified advanced non-small cell lung cancer (NSCLC)***
- ***Plan to provide detailed update for TRIDENT-1 registrational ROS1-positive NSCLC population and additional data for NTRK-positive solid tumor population, as well as SHIELD-1 Phase 1 data at medical conference in 2H 2022***
- ***On track to submit data to FDA to support elzovantinib recommended Phase 2 dose (RP2D) and for initiation of potentially registrational Phase 2 SHIELD-1 Study in 2H 2022, pending FDA feedback on data from the intermediate dose level***
- ***Definitive merger agreement with Bristol Myers Squibb to acquire Turning Point Therapeutics with transaction expected to close during the third quarter of 2022***
- ***Cash, Cash Equivalents, and Marketable Securities of Approximately $818 Million as of June 30, 2022***

SAN DIEGO, Aug. 08, 2022 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a clinical-stage precision oncology company designing and developing novel targeted therapies for cancer treatment, today reported financial results for the quarter ended June 30, 2022 and provided operational updates.

“We are pleased with our continued pipeline advancement and expansion,” said Athena Countouriotis, M.D., President and CEO. “We look forward to a productive second half of the year, with multiple data readouts and continued regulatory progress.”

Second quarter and recent operational highlights include:

REPOTRECTINIB:

- Announced receipt of positive feedback from the FDA at a pre-NDA meeting completed during the second quarter. The feedback focused on the proposed patient follow-up within the ROS1-positive advanced NSCLC patient cohorts of the ongoing TRIDENT-1 registrational study. The purpose of the pre-NDA meeting was to discuss the company’s planned NDA for repotrectinib for the treatment of ROS1+ advanced NSCLC. The FDA agreed with the company’s plan to provide data for ROS1+ TKI-naïve and TKI-pretreated advanced NSCLC patients with at least six months of follow-up from the first post-baseline scan at the time of NDA submission.
- Received Breakthrough Therapy designation (BTD) from the FDA for repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have been previously treated with one ROS1 tyrosine kinase inhibitor and who have not received prior platinum-based chemotherapy. This represents the eighth regulatory designation granted by the FDA for repotrectinib.

ELZOVANTINIB:

- Initiated the Phase 1b/2 SHIELD-2 combination study of elzovantinib and aumolertinib in EGFR mutant MET-amplified advanced non-small cell lung cancer. The combination of elzovantinib and aumolertinib is being studied in patients with EGFR mutant MET-amplified advanced NSCLC who have progressed following treatment with osimertinib. The study will evaluate the safety, tolerability and preliminary efficacy of the combination regimen.

TPX-4589

- Initiated patient dosing in the third dosing level cohort in the Phase 1 study of TPX-4589. TPX-4589 is a potentially first-in-class anti-Claudin18.2 antibody drug conjugate (ADC) that suppresses cell proliferation of gastric and pancreatic cell lines with nanomolar potency in preclinical models. It is currently being studied in two ongoing Phase 1 studies in patients with advanced solid tumors.

BUSINESS DEVELOPMENT:

- Announced a strategic research and development alliance with The University of Texas MD Anderson Cancer Center to expand the evaluation of repotrectinib and elzovantinib. The planned focus of the alliance includes monotherapy and potential combinations with other agents – including chemotherapy, immunotherapies and other targeted agents.
- Entered into an exclusive license agreement with LaNova Medicines Limited to develop and commercialize LM-302, now known as TPX-4589, a novel antibody drug conjugate targeting Claudin18.2, in the United States and rest of the world excluding Greater China and South Korea. Claudin18.2 is a protein expressed in many gastrointestinal cancers, including gastric, gastroesophageal junction and pancreatic cancer. TPX-4589 is currently in Phase 1 clinical trials in both the United States and China.
- Announced a definitive merger agreement with Bristol Myers Squibb to acquire Turning Point Therapeutics for $76.00 per share. The transaction was unanimously approved by both the Bristol Myers Squibb and Turning Point Therapeutics Boards of Directors and is anticipated to close during the third quarter of 2022.

Upcoming Milestones

REPOTRECTINIB

- Present detailed study results, including intracranial activity, from the ROS1-positive advanced NSCLC cohorts of the TRIDENT-1 study at a medical conference in the second half of 2022.
- Provide a clinical data update from the NTRK+ advanced solid tumor cohorts from TRIDENT-1 in the second half of 2022.

ELZOVANTINIB

- Initiate the Phase 2 portion of the SHIELD-1 study in the second half of 2022, pending FDA feedback on data from the intermediate dose level.
- Provide a clinical data update from the Phase 1 SHIELD-1 study in the second half of 2022.

TPX-0131

- Provide early interim data from initial patients treated in the dose-finding portion of the FORGE-1 study in the fourth quarter of 2022 or early 2023.

TPX-4589

- Present preclinical data at a medical conference by early 2023.
- Provide additional guidance on clinical development plan by early 2023.

DISCOVERY

- Nominate 2 development candidates in the second half of 2022.
- Provide details on the other 2 GTPase signaling discovery programs in the second half of 2022.

Second Quarter 2022 Financial Results

- Revenue: Revenue recognized during the second quarter of 2022 was $0.1 million from the sale of clinical supply to Zai Lab (Shanghai) Co. Ltd. (Zai), compared to $5.2 million during the second quarter of 2021, consisting of $5.0 million earned upon the achievement of development milestones under the license agreement with Zai regarding repotrectinib and $0.2 million from the sale of clinical supply to Zai.

- R&D Expenses: Research and development expenses were $86.8 million for the second quarter of 2022 compared to $44.7 million for the second quarter of 2021. Primary drivers of the year-over-year increase were investments made to develop repotrectinib, discovery efforts and personnel expenses. In addition, R&D expenses for the second quarter of 2022 included an upfront payment of $25.0 million to LaNova for the in-licensing of its intellectual property that has not yet achieved regulatory approval.

- G&A Expenses: General and administrative expenses were $37.7 million for the second quarter of 2022 compared to $17.2 million for the second quarter of 2021. G&A expenses for the second quarter of 2022 included approximately $17.7 million of transaction costs incurred in connection with the pending acquisition by Bristol Myers Squibb.

- Net Loss: Net loss was $123.1 million for the second quarter of 2022 compared to net loss of $56.3 million for the second quarter of 2021.

- Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2022 totaled $818.3 million, reflecting a

net decrease of approximately $99.9 million from March 31, 2022.

About Turning Point Therapeutics Inc.
Turning Point Therapeutics is a clinical-stage precision oncology company with a pipeline of 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 elzovantinib, 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; 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; and TPX-4589 (LM-302), a novel ADC targeting Claudin18.2 which is being studied in a Phase 1 study in gastrointestinal cancers. 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. Words such as "plans", "will", "believes," "anticipates," "expects," "intends," "goal," "potential" and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and therapeutic potential of Turning Point Therapeutics' drug candidates, repotrectinib, elzovantinib, TPX-0046, TPX-0131, and TPX-4589, 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 closing and proposed timing of the pending acquisition by Bristol Myers Squibb. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such 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 Therapeutics' business and the other risks described in Turning Point Therapeutics' filings with the Securities and Exchange Commission (SEC), including its quarterly report on Form 10-Q filed with the SEC on August 8, 2022. 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**)

	June 30, 2022	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 818,286	$ 981,582
Working capital	782,244	945,373
Total assets	843,335	1,003,463
Accumulated deficit	(714,260)	(516,727)
Total stockholders' equity	$ 793,022	$ 954,425

TURNING POINT THERAPEUTICS, INC.
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,	
	2022	2021	2022	2021
Revenue	$ 119	$ 5,164	$ 548	$ 30,369
Operating expenses:				
Research and development	86,788	44,650	141,838	85,913
General and administrative	37,695	17,171	58,009	37,162
Total operating expenses	124,483	61,821	199,847	123,075
Loss from operations	(124,364)	(56,657)	(199,299)	(92,706)
Other income, net	1,276	384	1,766	929
Net loss	(123,088)	(56,273)	(197,533)	(91,777)
Unrealized loss on marketable securities	(1,522)	(22)	(5,640)	(208)
Comprehensive loss	$ (124,610)	$ (56,295)	$ (203,173)	$ (91,985)

Net loss per share, basic and diluted	$ (2.48)	$ (1.14)	$ (3.98)	$ (1.87)
Weighted-average common shares outstanding, basic and diluted	49,702,860	49,204,425	49,657,426	49,063,298

Contact:
Adam D. Levy, Ph.D., M.B.A.
ir@tptherapeutics.com
858-867-6366

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