TCR² Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 12, 2022

- Initiated Phase 2 expansion portion of the ongoing gavo-cel clinical trial
- IND Clearance for Phase 1/2 clinical trial of TC-510
- 30 patients treated with gavo-cel in the expanded Phase 1 trial; dataset review in July 2022
- Updates anticipated in the second half of 2022

CAMBRIDGE, Mass., May 12, 2022 (GLOBE NEWSWIRE) -- TCR² Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage cell therapy company with a pipeline of novel T cell therapies for cancer patients suffering from solid tumors, today announced financial results for the first quarter ended March 31, 2022 and provided a corporate update.

“We are very pleased with the momentum generated in the last quarter as we initiated the next phases on two clinical programs and expect to present in July an expanded dataset on 30 patients treated with gavo-cel,” said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. “The consistent tumor regression observed with gavo-cel in Phase 1 establishes a baseline efficacy and safety profile upon which we can build in Phase 2. With the initiation of the TC-510 Phase 1 clinical trial, which includes the treatment of pancreatic cancer, colorectal cancer and triple negative breast cancer, we have an opportunity to expand the number of indications potentially addressable with our TRuC-T cell therapies. We look forward to a busy second half of execution as we scale these clinical trials as well as build out our preclinical pipeline targeting CD70 with enhancements and allogeneic strategies.”

Recent Developments

Gavo-cel:

- TCR² initiated the Phase 2 expansion portion of the ongoing Phase 1/2 clinical trial of gavo-cel, its first-in-class TRuC-T cell targeting mesothelin-expressing solid tumors. Enrollment is ongoing and the Company expects to report on progress from the Phase 2 portion of the clinical trial in the second half of 2022.
- TCR² announced the Company plans to present the expanded Phase 1 dataset for gavo-cel from the dose escalation portion of the Phase 1/2 clinical trial of gavo-cel in patients with treatment refractory mesothelin-expressing solid tumors in July 2022. The presentation will focus on safety, efficacy and translational data and include 30 patients from the Phase 1 dose escalation, with data from additional malignant pleural/peritoneal mesothelioma (MPM) and ovarian patients.

TC-510:

- TCR² announced the U.S. Food and Drug Administration (FDA) cleared the investigational new drug (IND) application for TC-510, a TRuC-T cell targeting mesothelin that co-expresses a PD-1:CD28 chimeric switch receptor. The Phase 1/2 clinical trial is evaluating the safety and efficacy of TC-510 in patients with mesothelin-expressing MPM, ovarian cancer, pancreatic cancer, colorectal cancer and triple negative breast cancer. The Company expects to report on progress from the Phase 1 portion of the clinical trial in the second half of 2022.

Anticipated Milestones

Gavo-cel:

- Present the expanded Phase 1 dataset for gavo-cel in July 2022.
- Provide an update from the Phase 2 portion of the ongoing gavo-cel Phase 1/2 clinical trial in the second half of 2022.

TC-510:

- Report initial safety, efficacy and translational data from at least one of the Phase 1 dose escalation cohorts of the TC-510 Phase 1/2 clinical trial in the second half of 2022.

Pipeline:

- Initiate IND-enabling studies for TC-520, an enhanced CD70 targeting TRuC-T cell program, in 2022.
- Select a lead candidate for its allogeneic program in 2022.

Manufacturing:

- Production of clinical trial material to commence at ElevateBio BaseCamp as capacity is increased in anticipation of

demand from the Phase 2 expansion trial of gavo-cel in 2022.

Financial Highlights

- **Cash Position**: TCR² ended the first quarter of 2022 with $232.2 million in cash, cash equivalents, and investments compared to $265.6 million as of December 31, 2021. Net cash used in operations was $31.1 million for the first quarter of 2022 compared to $23.9 million for the first quarter of 2021. TCR² projects net cash use of $115-125 million for 2022, the lower end of the range previously provided. We expect cash on hand to support operations into 2024.
- **R&D Expenses**: Research and development expenses were $22.9 million for the first quarter of 2022 compared to $15.9 million for the first quarter of 2021. The increase in R&D expenses was primarily due to an increase in headcount, clinical trial expenses associated with patient treatment and manufacturing, and manufacturing facilities expenses.
- **G&A Expenses**: General and administrative expenses were $6.3 million for the first quarter of 2022 compared to $5.7 million for the first quarter of 2021. The increase in general and administrative expenses was due to an increase in personnel costs and other professional fees.
- **Net Loss**: Net loss was $29.1 million for the first quarter of 2022 compared to $21.5 million for the first quarter of 2021.

Upcoming Events

TCR² Therapeutics management is scheduled to participate at the following upcoming conferences.

- H.C. Wainwright Global Investment Conference: Garry Menzel, President and Chief Executive Officer of TCR² Therapeutics, will present an update on Company progress on Tuesday, May 24, 2022 at 7:00am ET

About TCR² Therapeutics

TCR² Therapeutics Inc. is a clinical-stage cell therapy company developing a pipeline of novel T cell therapies for cancer patients suffering from solid tumors. The company is focused on the discovery and development of product candidates against novel and complex targets utilizing its proprietary T cell receptor (TCR) Fusion Construct T cells (TRuC®-T cells). The TRuC platform is designed to specifically recognize and kill cancer cells by harnessing signaling from the entire TCR, independent of human leukocyte antigens (HLA). For more information about TCR², please visit www.tcr2.com.

About gavo-cel

The ongoing gavo-cel Phase 1/2 clinical trial is evaluating the safety and efficacy of gavo-cel in patients with mesothelin-expressing MPM, ovarian cancer, non-small cell lung cancer (NSCLC) and cholangiocarcinoma.

In the Phase 2 portion of the clinical trial, patients will receive gavo-cel at the recommended Phase 2 dose (RP2D)($1x10^8$ cells/m^2). A total of 75 patients will be treated in the MPM cohort and a total of 20 patients will be treated in each one of the following indications: ovarian, NSCLC and cholangiocarcinoma. In the MPM cohort, patients will be randomized to receive either single agent gavo-cel, gavo-cel in combination with *Opdivo* (nivolumab), or gavo-cel in combination with *Opdivo* and *Yervoy* (ipilimumab). In ovarian, NSCLC and cholangiocarcinoma, all patients will receive gavo-cel in combination with *Opdivo*.

About TC-510

TC-510 is a mesothelin-targeted TRuC-T cell that co-expresses a PD-1:CD28 chimeric switch receptor to provide a local costimulatory signal by engaging with PD-L1 expressed in the hostile tumor microenvironment and converting the negative inhibitory signal into a positive costimulatory signal.

The TC-510 Phase 1/2 clinical trial is evaluating the safety and efficacy of TC-510 in patients with mesothelin-expressing MPM, ovarian cancer, pancreatic cancer, colorectal cancer and triple negative breast cancer.

The Phase 1 portion of the clinical trial utilizes a modified 3+3 design with five escalating dose levels for TC-510 ($50x10^6$, $100x10^6$, $130x10^6$, $160x10^6$, and $200x10^6$ cells). At each dose level, TC-510 will be treated with lymphodepletion chemotherapy and after the first patient is treated at each dose level, a 28-day safety observation period is instituted. Then, patients 2 and 3 may be infused simultaneously. The primary objective for the study is patient safety with a key secondary objective to determine the RP2D. In addition to standard measures of safety and efficacy, translational work includes the assessment of expansion, trafficking, and persistence of TC-510 T cells.

Forward-looking Statements

This press release contains forward-looking statements and information within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "will," "could", "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "seeks," "endeavor," "potential," "continue" or the negative of such words or other similar expressions can be used to identify forward-looking statements. These forward-looking statements include, but are not limited to, express or implied statements regarding the therapeutic potential of gavo-cel, TC-510 and the Company's other product candidates, expected progress and timing of updates for the gavo-cel and TC-510 clinical trials, expectations regarding clinical data for gavo-cel and TC-510 and preclinical data for our emerging pipeline and enhancements, increased manufacturing capacity and technical capabilities, including through our manufacturing partnership with ElevateBio, LLC, expectations with respect to increased clinical trial demand, future IND-enabling studies and filings, future clinical development plans, expected cash use in 2022 and cash runway into 2024, the development of the Company's TRuC-T cells, their potential characteristics, applications and clinical utility, and the potential therapeutic applications of the Company's TRuC-T cell platform.

The expressed or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in clinical studies and in the availability and timing of data from

ongoing clinical studies; whether interim results from a clinical trial will be predictive of the final results of the trial; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials; the expected timing of submissions for regulatory approval or review by governmental authorities, including review under accelerated approval processes; orphan drug designation eligibility; regulatory approvals to conduct trials or to market products; TCR²'s ability to maintain sufficient manufacturing capabilities to support its research, development and commercialization efforts, including TCR²'s ability to secure additional manufacturing facilities; whether TCR²'s cash resources will be sufficient to fund TCR²'s foreseeable and unforeseeable operating expenses and capital expenditure requirements, the impact of the COVID-19 pandemic on TCR²'s ongoing operations; and other risks set forth under the caption "Risk Factors" in TCR²'s most recent Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q and its other filings with the Securities and Exchange Commission. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although TCR² believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur.

Moreover, except as required by law, neither TCR² nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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TCR²THERAPEUTICS INC.
UNAUDITED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share data)

	March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 74,117	$ 222,564
Investments	158,071	43,029
Prepaid expenses and other current assets	15,115	10,534
Total current assets	247,303	276,127
Property and equipment, net	18,767	17,075
Right-of-use assets, operating leases	55,228	28,283
Restricted cash	1,158	1,156
Other assets, non-current	791	730
Total assets	$ 323,247	$ 323,371
Liabilities and stockholders' equity		
Accounts payable	$ 4,482	$ 2,144
Accrued expenses and other current liabilities	9,452	13,094
Operating lease liabilities	16,933	3,367
Total current liabilities	30,867	18,605
Operating lease liabilities, non-current	36,751	22,996
Other liabilities	313	293
Total liabilities	67,931	41,894
Stockholders' equity		
Common stock, $0.0001 par value; 150,000,000 shares authorized; 38,546,345 and 38,496,484 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively.	4	4
Additional paid-in capital	634,300	631,008
Accumulated other comprehensive income (loss)	(344)	(13)
Accumulated deficit	(378,644)	(349,522)
Total stockholders' equity	255,316	281,477
Total liabilities and stockholders' equity	$ 323,247	$ 323,371

TCR²THERAPEUTICS INC.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses		
Research and development	$ 22,883	$ 15,924
General and administrative	6,320	5,668
Total operating expenses	29,203	21,592
Loss from operations	(29,203)	(21,592)
Interest income, net	117	116
Loss before income tax expense	(29,086)	(21,476)
Income tax expense	36	36
Net loss	$ (29,122)	$ (21,512)
Per share information		
Net loss per share of common stock, basic and diluted	$ (0.76)	$ (0.58)
Weighted average shares outstanding, basic and diluted	38,513,104	37,062,604

TCR²THERAPEUTICS INC.
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	Three Months Ended March 31,	
	2022	**2021**
Operating activities		
Net loss	$ (29,122)	$ (21,512)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	706	513
Stock-based compensation expense	3,177	3,120
Amortization on investments	20	164
Deferred tax liabilities	21	36
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,400)	(2,265)
Operating leases, net	375	(3,808)
Accounts payable	1,756	1,684
Accrued expenses and other liabilities	(3,667)	(1,859)
Cash used in operating activities	(31,134)	(23,927)
Investing activities		
Purchases of equipment	(1,911)	(1,491)
Software development costs	(66)	-
Purchases of investments	(148,382)	(40,732)
Proceeds from sale or maturity of investments	32,989	59,287
Cash provided by (used in) investing activities	(117,370)	17,064
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	-	131,330
Proceeds from the exercise of stock options	115	376
Payment of deferred offering costs	(56)	(164)
Cash provided by financing activities	59	131,542
Net change in cash, cash equivalents, and restricted cash	(148,445)	124,679
Cash, cash equivalents, and restricted cash at beginning of year	223,720	94,738
Cash, cash equivalents, and restricted cash at end of period	$ 75,275	$ 219,417

Source: TCR2 Therapeutics