TCR² Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

March 30, 2020

- Company initiated Phase 1/2 clinical trial for TC-110, its lead hematological malignancy candidate
- Interim update from Phase 1 portion of TC-210 Phase 1/2 trial anticipated in 2Q20 and Phase 1/2 trial of TC-110 in 2H20
- TCR^2 manufacturing suite fully operational in Stevenage, United Kingdom

CAMBRIDGE, Mass., March 30, 2020 (GLOBE NEWSWIRE) -- TCR^2 Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer, today announced financial results for the fourth quarter and full year ended December 31, 2019 and provided a corporate update.

“The past twelve months represent an exciting period for TCR^2 as we advanced two programs into clinical trials. Last year we began using TC-210 to treat patients with mesothelin-positive solid tumors and, more recently, we initiated a Phase 1/2 trial of TC-110 in patients with CD19-positive hematological malignancies because we believe that TRuC-T cells alone can improve on the benefit provided by approved CAR-Ts,” said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR^2 Therapeutics. “Looking ahead, 2020 is a pivotal year for the Company with interim Phase 1 data for both TC-210 and TC-110 as well as updates on new targets, our platform enhancements and allogeneic TRuC-T cells. With a year-end 2019 cash balance of $158.1 million, we are in a strong financial position to maintain runway into 2022 and execute on our strategic priorities.”

“Commercially available CD19 CAR-Ts provide durable benefit in fewer than half of patients with lymphoma and their approval in acute lymphoblastic leukemia (ALL) remains limited to pediatric patients because they result in excessive toxicity in adult patients, as I witnessed while developing Kymriah,” said Alfonso Quintás Cardama, M.D., Chief Medical Officer of TCR^2 Therapeutics. “Our TRuC T-cells are more effective at trafficking in solid tumor models, which lymphoma tumors resemble, and are metabolically fitter than CAR-Ts, which enhances their ability to persist longer within the immunosuppressive solid tumor microenvironment. This gives us confidence that TC-110 may be more effective in treating patients with lymphoma and could allow us to salvage those who have previously failed CD19-directed CAR-Ts. In addition, we have shown that TRuC-T cells consistently release lower levels of cytokines in preclinical experiments, which could translate into a more favorable toxicity profile that would allow us to treat adult patients with ALL more safely.”

Recent Developments

- The U.S. Food and Drug Administration cleared the investigational new drug (IND) application for TC-110. TCR^2 initiated its Phase 1/2 trial to treat patients with CD19-positive B-cell hematological malignancies, including adult acute lymphoblastic leukemia (aALL), diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), and other non-Hodgkin lymphoma (NHL) subtypes.
- TCR^2 established operational capabilities at its manufacturing facility in Stevenage, UK and expects to use the facility to manufacture and supply clinical material after approval by the UK Medicines and Healthcare Regulatory Agency (MHRA).
- TCR^2 presented a poster at the 2020 Keystone Symposia Conference on Emerging Cellular Therapies: Cancer and Beyond highlighting allogeneic (off-the-shelf) T Cell Receptor Fusion Constructs (TRuC®) T cells that lack alloreactivity and upregulate activation markers, secrete cytokines and kill tumor cells in an antigen-specific manner.
- COVID-19 has significantly impacted the global healthcare system, including the conduct of clinical trials as medical institutions prioritize the treatment of those afflicted with COVID-19. As we balance the commitment to treat our cancer patients while mitigating the risk of viral spread to patients, employees and their families, we have instituted protective policies consistent with guidelines provided by the Centers for Disease Control and Prevention at all TCR^2 facilities. While we are committed to providing an interim update of the Phase 1 portion of the TC-210 Phase 1/2 clinical trial in the second quarter of 2020 and the Phase 1 portion of the TC-110 Phase 1/2 clinical trial in the second half of 2020, the effect of the COVID-19 pandemic may impact the exact timing or content of these interim updates.

TC-110 Clinical Trial Design

- The Phase 1/2 clinical trial is evaluating the safety and efficacy of TC-110, TCR^{2}s TRuC-T cell targeting CD19. The trial is enrolling patients with CD19-positive B-cell hematological malignancies including aALL, DLBCL, FL and other NHL subtypes.
- In the Phase 1 portion of the clinical trial, patients will receive increasing TC-110 T cell doses following lymphodepleting chemotherapy. The primary objective of the Phase 1 portion of the study is to assess safety with a key secondary objective to determine the recommended Phase 2 dose (RP2D).
- In the Phase 2 portion of the clinical trial, approximately 60 patients are planned to receive TC-110 at the RP2D and will be

stratified according to their cancer diagnosis in three distinct cohorts: aggressive NHL, indolent NHL and aALL. Approximately 20 patients per indication will be infused with TC-110 T cells.
- In addition to standard assessments of safety and efficacy, a panel of translational assays will be performed on patient samples throughout both phases of the study to assess, among others, cytokine production as well as expansion, trafficking, persistence, and changes in immunophenotype of TC-110 T cells.

TC-110 Patient Opportunity

Adult ALL

- In 2019, there were an estimated 5,900 cases of ALL and over 1,500 related deaths in the United States. Adults comprise approximately 45% of all ALL cases but make up more than 85% of ALL-related deaths. CD19 directed CAR-Ts are not approved for patients with aALL.

DLBCL

- In 2019 there were an estimated 74,000 new cases of NHL and 20,000 related deaths in the United States. Approximately two-thirds of patients with DLBCL are cured of their disease with frontline chemoimmunotherapy (R-CHOP). However, refractory patients have a median overall survival of only 6.3 months.
- CD19-directed CAR-T cell therapy has shown activity in heavily pre-treated patients with CD19-positive DLBCL and two CAR-T cell therapies, Kymriah and Yescarta, have been approved for that indication. However, the response rate six months post-infusion ranges from 37% to 41% and both therapies are associated with high rates of severe CRS (13% to 23%) and neurotoxicity (12% to 28%).

Follicular Lymphoma

- Approximately 15,000 patients were diagnosed in the United States with FL in 2019. The clinical course of patients with FL is generally indolent. However, 20% of patients with FL relapse within two years of R-CHOP therapy and have a median five-year survival rate of only 50% compared to 90% for the remaining 80% of patients with a longer response duration. The experience with CAR-T cell therapy in FL is much more limited than in ALL or DLBCL.

Anticipated Milestones

- TCR^2 anticipates an interim update from the Phase 1 portion of the TC-210 Phase 1/2 clinical trial for patients with mesothelin-expressing solid tumors in 2Q20.
- TCR^2 anticipates an interim update from the Phase 1 portion of the TC-110 Phase 1/2 clinical trial for patients with CD19+ non-Hodgkin lymphoma or adult acute lymphoblastic leukemia in 2H20.
- TCR^2 anticipates clinical production of TRuC-T cells at its manufacturing facility in Stevenage, UK, in 2H20.
- TCR^2 anticipates advancing a third mono TRuC-T cell therapy in 2Q20 with a target IND filing in 1H21.

Financial Highlights

- **Cash Position**: TCR^2 ended 2019 with $158.1 million in cash, cash equivalents, and investments compared to $123.2 million as of December 31, 2018. Net cash used in operations was $41.4 million for 2019 compared to $18.7 million for 2018. TCR^2 projects net cash use of $60-70 million for 2020.

- **R&D Expenses**: Research and development expenses were $37.5 million for 2019 compared to $19.7 million for 2018. The increase in R&D expenses is primarily related to increase in headcount, activities related to the Phase 1/2 clinical trial of the Company's lead solid tumor product candidate, TC-210, and activities related to the IND submission of the Company's lead hematologic cancer product candidate, TC-110.

- **G&A Expenses**: General and administrative expenses were $13.9 million for 2019 compared to $6.8 million for 2018. The increase in general and administrative expenses was primarily due to an increase in personnel costs and costs associated with operations as a public company.

- **Net loss**: Net loss was $47.6 million for 2019 compared to $24.3 million for 2018, driven predominantly by increased R&D expense for 2019.

Upcoming Events

TCR^2 Therapeutics management are scheduled to participate at the following upcoming conferences.

·Goldman Sachs Cell Therapy Day: Alfonso Quintás Cardama, M.D., Chief Medical Officer of TCR^2 Therapeutics, will present using a virtual platform on Monday, April 6, 2020 at 2:00pm ET

About TCR^2 Therapeutics

TCR^2 Therapeutics Inc. is a clinical-stage immunotherapy company developing the next generation of novel T cell therapies for patients suffering from cancer. TCR^{2}s proprietary T cell receptor (TCR) Fusion Construct T cells (TRuC ®-T cells) specifically recognize and kill cancer cells by harnessing signaling from the entire TCR, independent of human leukocyte antigens (HLA). In preclinical studies, TRuC-T cells have demonstrated superior anti-tumor activity compared to chimeric antigen receptor T cells (CAR-T cells), while exhibiting lower levels of cytokine release. The Company's lead TRuC-T cell product candidate targeting solid tumors, TC-210, is currently being studied in a Phase 1/2 clinical trial to treat patients with mesothelin-positive non-small cell lung cancer (NSCLC), ovarian cancer, malignant pleural/peritoneal mesothelioma, and cholangiocarcinoma. The Company's lead TRuC-T cell product candidate targeting hematological malignancies, TC-110, is currently being studied in a Phase 1/2 clinical trial to treat patients with CD19-positive adult acute lymphoblastic leukemia (aALL) and with aggressive or indolent non-Hodgkin lymphoma (NHL). For more information about TCR^2, please visit www.tcr2.com.

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 anticipated timing of updates from TCR^{2}s ongoing Phase 1 portion of the TC-210 clinical trial in 2Q20 and the ongoing Phase 1 portion of the TC-110 clinical trial in 2H20, anticipated clinical production of TRuC-T cells at TCR^{2}s manufacturing facility in Stevenage, UK, in 2H20, anticipated patient populations for TC-110, anticipated updates on new targets, platform enhancements and IND filings, and TCR^{2}s expectations with respect to its financial resources and the impact that the current COVID-19 pandemic will have on the Company's clinical trials and operations.

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; TCR^{2}s ability to maintain sufficient manufacturing capabilities to support its research, development and commercialization efforts, whether TCR^2's cash resources will be sufficient to fund TCR^2's foreseeable and unforeseeable operating expenses and capital expenditure requirements; the risk that the current COVID-19 pandemic will impact the Company's clinical trials and other operations; and other risks set forth under the caption "Risk Factors" in TCR^{2}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 TCR^2 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 TCR^2 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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TCR^2 THERAPEUTICS INC.
UNAUDITED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share data)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 65,296	$ 47,674
Investments	92,828	75,493
Prepaid expenses and other current assets	5,061	2,326
Total current assets	163,185	125,493
Property and equipment, net	4,926	1,638
Restricted cash	417	290

Deferred offering costs	-	2,012
Total assets	$ 168,528	$ 129,433
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Accounts payable	$ 2,483	$ 2,663
Accrued expenses and other current liabilities	5,050	2,802
Total current liabilities	7,533	5,465
Other liabilities	546	434
Total liabilities	8,079	5,899
Redeemable convertible preferred stock		
Series A preferred stock, $0.0001 par value; no shares and 45,000,000 authorized; no shares and 44,500,001 shares issued and outstanding at December 31, 2019 and 2018, respectively.	-	72,980
Series B preferred stock, $0.0001 par value; no shares and 62,500,000 authorized, issued, and outstanding at December 31, 2019 and 2018, respectively.	-	136,250
Total redeemable convertible preferred stock	-	209,230
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value. 10,000,000 shares and no shares authorized, no shares issued or outstanding at December 31, 2019 and 2018, respectively.	-	-
Common stock, $0.0001 par value; 150,000,000 and 20,988,730 shares authorized; 24,050,936 and 914,602 shares issued; 23,981,109 and 726,990 shares outstanding at December 31, 2019 and 2018, respectively.	2	-
Additional paid-in capital	342,896	-
Accumulated other comprehensive income (loss)	142	(106)
Accumulated deficit	(182,591)	(85,590)
Total stockholders' equity (deficit)	160,449	(85,696)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 168,528	$ 129,433

TCR^2 THERAPEUTICS INC.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating expenses				
Research and development	$ 9,392	$ 6,219	$ 37,488	$ 19,673
General and administrative	4,179	2,222	13,894	6,780
Total operating expenses	13,571	8,441	51,382	26,453

Loss from operations	(13,571)	(8,441)	(51,382)	(26,453)
Interest income, net	846	751	3,885	2,202
Loss before income taxes	(12,725)	(7,690)	(47,497)	(24,251)
Income taxes	102	-	102	-
Net loss	(12,827)	(7,690)	(47,599)	(24,251)
Accretion of redeemable convertible preferred stock to redemption value	-	(3,730)	(49,900)	(37,298)
Net loss attributable to common stockholders	$ (12,827)	$ (11,420)	$ (97,499)	$ (61,549)
Per share information				
Net loss per share of common stock, basic and diluted	$ (0.54)	$ (16.22)	$ (4.62)	$ (98.53)
Weighted average shares outstanding, basic and diluted	23,961,960	703,874	21,104,195	624,659

TCR^2 THERAPEUTICS INC.
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	Years Ended December 31,	
	2019	**2018**
Operating activities		
Net loss	$ (47,599)	$ (24,251)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	862	419
Stock-based compensation expense	6,702	2,133
Accretion on investments	(225)	(280)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,057)	(1,433)
Accounts payable	(179)	2,224
Accrued expenses and other liabilities	2,137	2,450
Cash used in operating activities	(41,359)	(18,738)
Investing activities		
Purchase of investments	(126,261)	(97,810)
Proceeds from sale or maturity of investments	109,725	22,490
Purchases of equipment	(3,879)	(1,019)
Cash used in investing activities	(20,415)	(76,339)
Financing activities		
Proceeds from the sale of Series B preferred stock, net of issuance costs	-	124,830
Proceeds from initial public offering, net of issuance costs	79,132	-

Proceeds from the exercise of stock options	391	100
Deferred offering costs	-	(1,990)
Cash provided by financing activities	79,523	122,940
Net increase in cash, cash equivalents, and restricted cash	17,749	27,863
Cash, cash equivalents, and restricted cash at beginning of year	47,964	20,101
Cash, cash equivalents, and restricted cash at end of period	$ 65,713	$ 47,964

Source: TCR2 Therapeutics