

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Act of 1934

Date of Report (Date of earliest event reported):
December 14, 2020 (December 13, 2020)

TCR² THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38811
(Commission
File Number)

47-4152751
(I.R.S. Employer
Identification Number)

100 Binney Street, Suite 710
Cambridge, Massachusetts
(Address of principal executive offices)

02142
(Zip Code)

Registrant's telephone number, including area code: (617) 949-5200

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13d-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TCRR	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 13, 2020, TCR2 Therapeutics Inc. (the “Company”) issued a press release titled “TCR2 Therapeutics Announces RECIST Response in Ovarian Cancer from Ongoing Phase 1/2 Trial of TC-210 in Treatment Refractory Mesothelin-Expressing Solid Tumors.” A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information under this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished herewith and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

The Company from time to time presents and/or distributes to the investment community slide presentations to provide updates and summaries of its business. On December 14, 2020, the Company will host a conference call and webcast to discuss interim data from the Phase 1 portion of the TC-210 Phase 1/2 clinical trial for patients with mesothelin-expressing solid tumors. A copy of its “Presentation of Interim Clinical Data from Gavo-cel (TC-210) Patients” slide presentation is being filed herewith as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

Statements contained under this Item 8.01, including Exhibit 99.2, regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to: TCR2’s guidance regarding TC-210, including the therapeutic potential and clinical benefits thereof, as well as the safety and tolerability of TC-210 and future clinical development plans; TCR2’s ongoing Phase 1/2 clinical trial of TC-210, including its interim results; and the potential impact of COVID-19 on the Company’s strategy, future operations and clinical trials.

Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include, 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, 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. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release issued by TCR2 Therapeutics Inc. on December 13, 2020.</u>
99.2	<u>Copy of TCR2 Therapeutics Inc. slide presentation dated December 14, 2020</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TCR² THERAPEUTICS INC.

By: /s/ Mayur (Ian) Somaiya
Name: Mayur (Ian) Somaiya
Title: Chief Financial Officer

Date: December 14, 2020



TCR² Announces RECIST Response in Ovarian Cancer from Ongoing Phase 1/2 Trial of TC-210 in Treatment Refractory Mesothelin-Expressing Solid Tumors

- TC-210 induced tumor regression in all of the first eight patients
- Ovarian cancer patient achieved confirmed RECIST partial response (PR)
- Overall response rate (ORR) 50% in patients infused with TC-210 and lymphodepletion
- Continued manageable toxicity profile
- Phase 1 trial amended to accelerate treatment
- TCR² to host conference call Monday, December 14 starting at 8:00am E.T. live webcast available

CAMBRIDGE, Mass., December 13, 2020—TCR² Therapeutics Inc. (Nasdaq: TCRR), a clinical-stage immunotherapy company with a pipeline of novel T cell therapies for patients suffering from cancer, today announced positive interim data from the ongoing Phase 1 portion of the TC-210 (gavocabtagene autoleucel or “gavo-cel”) Phase 1/2 clinical trial for mesothelin-expressing solid tumors. As of the November 24, 2020 data cutoff, three PRs according to RECIST 1.1 criteria have been recorded among the first eight patients treated on study, with our first ovarian cancer patient having achieved a confirmed PR up to month six. In addition, the first patient treated at a higher gavo-cel dose (1x10⁸/m²) without lymphodepletion achieved stable disease through two months without any significant toxicities, which has allowed patients to start treatment at that dose with the addition of lymphodepletion. The toxicity profile remains manageable with only two patients to date exhibiting gavo-cel-related non-hematologic grade >2 toxicity and no evidence of neurotoxicity or on-target, off-tumor toxicity. Translational data further demonstrated TRuC-T cell expansion and cytokine induction in all patients.

“Although the focus of any Phase 1 trial is safety, the consistency in tumor regression and RECIST responses we have observed with gavo-cel as a single agent supports our belief in the advantages of TRuC-T cells over other cell therapies and the potential for a fundamentally new approach in the treatment of solid tumors,” said Garry Menzel, Ph.D., President and Chief Executive Officer of TCR² Therapeutics. “The HLA independence of our technology allows us to treat a broad population of patients with mesothelin surface expression while leveraging the full T cell receptor complex to drive enhanced trafficking, on-target killing and persistence in the hostile solid tumor microenvironment. Most important, we are delivering clinical and survival benefit to those patients with heavily pre-treated mesothelioma or ovarian cancer.”

“The ability of gavo-cel to benefit patients who have become treatment refractory after having failed multiple lines of therapy, including immune checkpoint inhibitors and anti-mesothelin therapy, combined with its manageable safety profile is remarkable. The changes announced today to the Phase 1 trial design, reducing the intra-cohort safety observation periods to 14 days from 28 days, enable us to more rapidly identify the recommended Phase 2 dose and initiate the Phase 2 expansion trial where we will evaluate the efficacy of gavo-cel in four solid tumor indications. Importantly, in the Phase 2 we will explore the impact of gavo-cel retreatment and its combination with checkpoint inhibitor therapy which could further improve on the clinical benefit observed to date,” said Alfonso Quintás-Cardama, M.D., Chief Medical Officer of TCR² Therapeutics.

The primary objectives of the Phase 1 portion of the study are to define the safety profile of gavo-cel in patients whose tumors overexpress mesothelin and to determine the recommended Phase 2 dose (RP2D). Secondary objectives include ORR and disease control rate (DCR). Exploratory objectives include the assessment of expansion, tumor infiltration, and persistence of gavo-cel.

Summary of trial conduct, baseline characteristics and gavo-cel dose:

- **Safety Protocol:** The new clinical trial protocol amendment allows the intra-cohort safety observation periods to be reduced to 14 days from 28 days, allowing the testing of a gavo-cel dose over a minimum of 56 days compared to the previous 84 days.
- **Screening:** Forty-five percent of patients met the mesothelin expression cut-off as defined per protocol.
- **Manufacturing:** Products meeting protocol defined specifications for gavo-cel have been manufactured successfully for each patient from whom apheresis material was sent into production.
- **Patient Characteristics:** Eight patients received gavo-cel including seven with mesothelioma and one with ovarian cancer with a median age of 65 years (range, 36-84 years). The median number of prior therapies was 5.5 (range, 3-9), including immune checkpoint inhibitor therapy (n=6) and anti-mesothelin therapies (n=3).
- **Gavo-cel Dose:** The eight patients disclosed to date have received gavo-cel at the following dose level (DL):
 - **DL 0:** 5×10^7 cells/m² without lymphodepletion – 1 mesothelioma
 - **DL 1:** 5×10^7 cells/m² following lymphodepletion – 5 mesothelioma and 1 ovarian cancer
 - **DL 2:** 1×10^8 cells/m² without lymphodepletion – 1 mesothelioma

Key clinical findings from the first eight patients treated with gavo-cel:

- **Safety:** Gavo-cel was generally well tolerated, with no patients experiencing neurotoxicity or on-target, off-tumor toxicities. Two (25%) patients experienced Cytokine Release Syndrome (CRS) grade 3, which was successfully managed with tocilizumab and corticosteroids.
- **Clinical Activity:** All eight patients have had at least one disease response assessment. The DCR was 100%, with all patients experiencing tumor regression. The median decrease in the sum of diameters of target lesions was 43% (range, 5% to 75%). The ORR was 38% (2 confirmed and 1 unconfirmed PRs) according to RECIST v1.1 criteria, including one patient who achieved a complete metabolic response.
- **Translational Data:** Peak gavo-cel expansion (C_{\max}) occurred between days 7 and 23. C_{\max} increased when gavo-cel was administered following lymphodepletion. The median peak gavo-cel expansion was 811.9 copies/μg of genomic DNA (range, 520 to 5,901 copies/μg). Cytokine induction post-gavo-cel infusion was observed in all evaluable patients, which is indicative of mesothelin target engagement.

About the Phase 1/2 Clinical Trial in Advanced Mesothelin-Expressing Solid Tumors

The Phase 1/2 clinical trial (NCT03907852) is evaluating the safety and efficacy of gavocabtagene autoleucel ("gavo-cel"; TC-210), TCR2's T cell receptor fusion construct directed against mesothelin. The trial is enrolling patients with mesothelin expressing NSCLC, ovarian cancer, cholangiocarcinoma, and malignant pleural/peritoneal mesothelioma. The Phase 1 dose escalation portion of the clinical trial utilizes a modified 3+3 design with four increasing gavo-cel doses. At each dose, gavo-cel will be tested in two separate dose levels: first without lymphodepletion and then following lymphodepleting chemotherapy. The Phase 1 portion of the clinical trial is ongoing.

In the Phase 2 portion of the clinical trial, approximately 50 patients are planned to receive gavo-cel at the RP2D in four distinct cohorts according to their cancer diagnosis: NSCLC, ovarian cancer, malignant pleural/peritoneal mesothelioma and cholangiocarcinoma. Each cohort will include ten patients, except the NSCLC cohort which will include 20 patients with eight patients to receive gavo-cel as single agent and 12 patients to receive gavo-cel in combination with a programmed cell death 1 (PD-1) blocking antibody.

About Mesothelin-Expressing Solid Tumors

Mesothelin is a cell-surface glycoprotein highly expressed in a wide range of solid tumors, including malignant pleural/peritoneal mesothelioma, ovarian cancer, cholangiocarcinoma, breast cancer, pancreatic cancer and others. Overexpression of mesothelin is associated with poorer prognosis in some cancers due to its active role in both malignant transformation and tumor aggressiveness by promoting cancer cell proliferation, invasion, and metastasis. Of the wide range of solid tumors expressing mesothelin, non-small cell lung cancer, ovarian cancer, mesothelioma and cholangiocarcinoma represent a patient population up to 80,000 annually in the United States alone.

TCR2 Therapeutics Conference Call and Webcast

TCR2 Therapeutics will host a conference call and webcast on Monday, December 14th at 8:00am E.T. The webcast and presentation will be made available on the TCR2 Therapeutics website in the Investors section under Events at <http://investors.tcr2.com/events>. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

About TCR2 Therapeutics

TCR2 Therapeutics Inc. is a clinical-stage immunotherapy company developing a pipeline of novel T cell therapies for patients suffering from solid tumors or hematological malignancies. TCR2'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 secreting lower levels of cytokine release. The Company's lead TRuC-T cell product candidate targeting solid tumors, gavo-cel, 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 TCR2, 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 the therapeutic potential of gavo-cel, future clinical development plans, 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, 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.

Investor and Media Contact:

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Director, Investor Relations and Corporate Communications
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POWERING THE TCR
TO TRANSFORM THE LIVES OF
CANCER PATIENTS WITH
SOLID TUMORS

**Interim Clinical Data from
Gavo-cel (TC-210) Patients**

December 2020



Forward Looking Statements

This presentation has been prepared by TCR² Therapeutics Inc. ("we," "us," or "our") and contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our development plans, our clinical results and other future conditions. All statements, other than statements of historical facts, contained in this presentation, including express or implied statements regarding our expectations for the Phase 1/2 clinical trials of Gavo-cel and TC-110, our expectations for the safety and efficacy of our product candidates, including Gavo-cel and TC-110, compared to current T-cell therapy approaches, and our expectations regarding the estimated patient populations and related market opportunities in Gavo-cel's and TC-110's targeted indications, are forward-looking statements. These statements are based on management's current expectations and beliefs and are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Such risks and uncertainties include, among others: 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 a trial; the possibility that positive results from preclinical studies and correlative studies may not necessarily be predictive of the results of our planned clinical trials, including the Phase 1/2 clinical trials of Gavo-cel and TC-110; the risk that the results from the Phase 1/2 clinical trials of Gavo-cel and

TC-110 will not support further development and marketing approval; the risk that we may be unable to gain approval of Gavo-cel, TC-110 and our other product candidates on a timely basis, if at all; the risk that we have over-estimated the potential patient population for our product candidates, if approved; the risk that the current COVID-19 pandemic will impact our clinical trials and other operations; and the other risks set forth under the caption "Risk Factors" in our most recent Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 30, 2020, as updated in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, as filed with the SEC on May 14, 2020, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, as filed with the SEC on August 12, 2020, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as filed with the SEC on November 12, 2020, and in our future filings with the SEC available at the SEC's website at www.sec.gov. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. You should not place undue reliance on any forward-looking statements, which speak only as of the date they are made.

While we may elect to update these forward-looking statements at some point in the future, we assume no obligation to update or revise any forward-looking statements except to the extent required by applicable law. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.



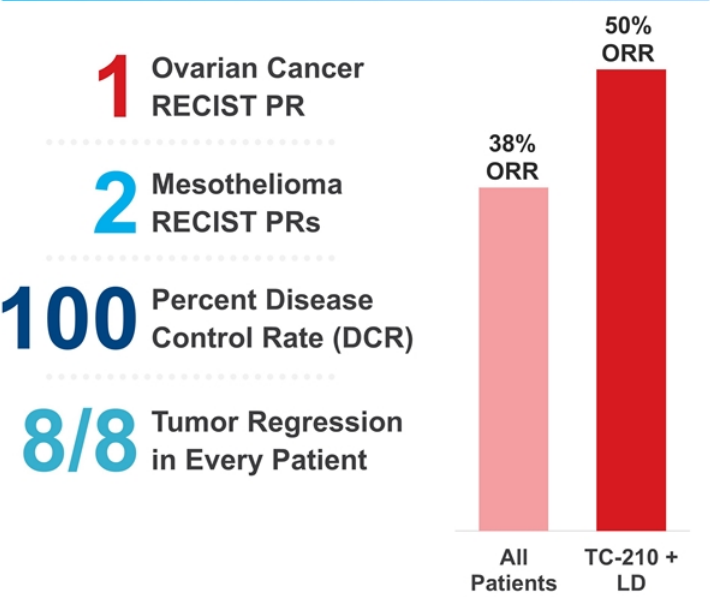
Introduction

Chief Executive Officer



Key Takeaways from First Eight TC-210 Patients

Clinical Responses



Manageable
Safety Profile



Patients Eligible for
TC-210 Based on
Mesothelin Threshold



Manufacturing
Success Rate



New, Shorter Safety
Observation Period

Generic TC-210 Name

gavocabtagene autoleucel (“gavo-cel”)



LD, Lymphodepletion; PR, Partial Response; ORR, Overall Response Rate

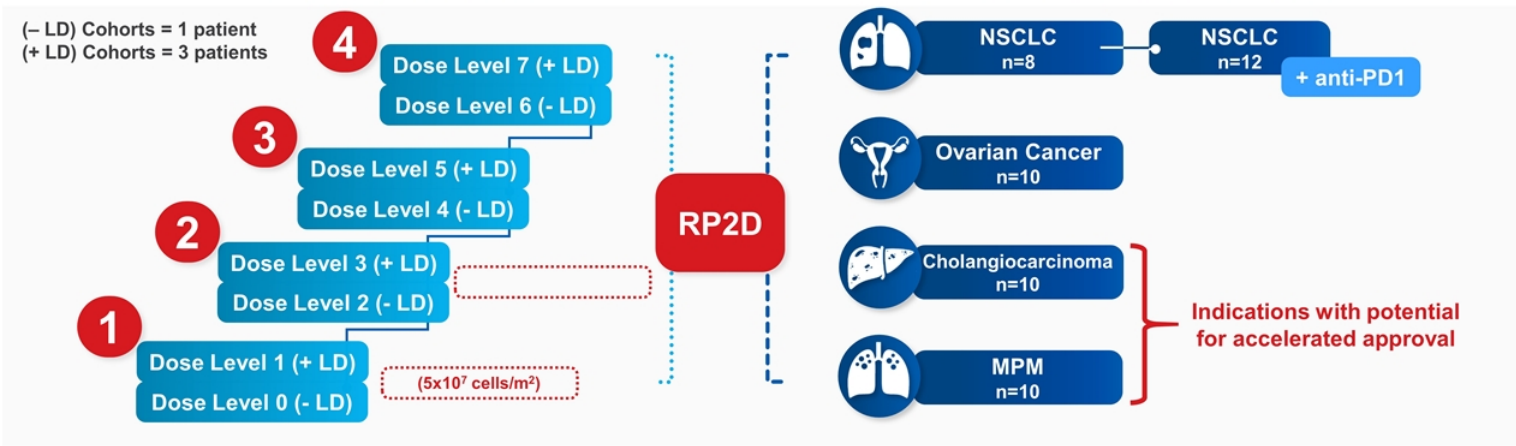
Gavo-cel Clinical Trial Review

Chief Medical Officer



Gavo-cel Phase 1/2 Trial in MSLN+ Solid Tumors

PHASE 1: Dose Finding



Phase 1 Objectives



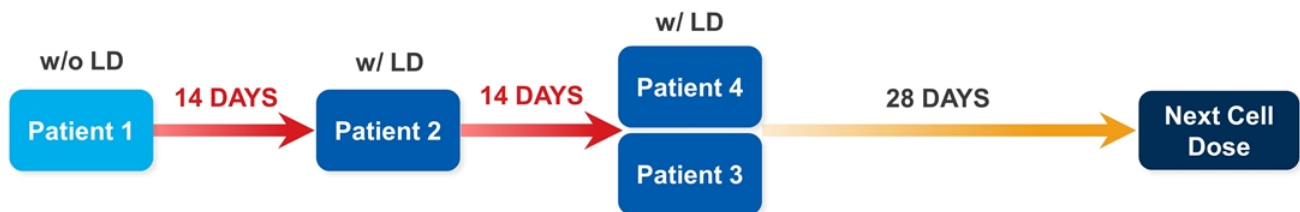
LD, Lymphodepletion; RP2D, Recommended Phase 2 dose; MPM, Malignant Pleural/Peritoneal Mesothelioma; NSCLC, Non-Small Cell Lung Cancer



Accelerated Dose Escalation Enrollment

Modified 3+3 Dose Escalation; 14-Day Intra-Cohort Safety Observation Periods

Each Dosing Cohort Consists of:



- Reduction of intra-cohort safety observation periods to 14 days from 28 days
- Accelerated path to identification of RP2D and initiation of Phase 2 expansion trial



LD, Lymphodepletion; RP2D, Recommended Phase 2 dose

Pre-Screening, Enrollment and Manufacturing Activity

Patients Pre-Screened	119
Tumor Samples Evaluable	87
MSLN 2+/3+ in $\geq 50\%$ Viable Tumor Cells n (%)	39 (45)
Patients Enrolled	26
Patients Apheresed	23
Patients Manufactured	17

Data Cutoff – November 24, 2020



Patient Characteristics

Characteristics	N = 8
Median age, years (range)	64.5 (36-84)
Cancer diagnosis	
Mesothelioma	7 (5 peritoneal, 2 pleural)
Ovarian cancer	1
Median No. of prior therapies (range)	5.5 (2-9)
≥4 prior therapies, No. (%)	5 (63)
Prior ICI therapy, No. (%)	6 (75)
Prior anti-MSLN directed therapy, No. (%)	3 (38)

Data Cutoff – November 24, 2020



ICI: immune checkpoint inhibitor; MSLN: mesothelin

Summary of Grade ≥ 3 Treatment Emergent Adverse Events

Adverse Event	N = 8 (%)
Hematologic	
Neutropenia	6 (75)
Lymphopenia	7 (88)
Thrombocytopenia	2 (25)
Adverse Events of Special Interest	
<i>On Target / On Tumor</i>	
CRS	2 (25)
Neurotoxicity	0
<i>On Target / Off Tumor</i>	
Pericarditis / Pericardial effusion	0
Pleuritis / Pleural effusion	0
Peritonitis / Ascites	0
<i>Infection / Inflammation</i>	
Pneumonitis*	1 (13)
Sepsis*	1 (13)

*Occurred in same patient who experienced Grade 3 CRS

Data Cutoff – November 24, 2020



RECIST v1.1 Response Assessment Summary

Dose Level	0	1	1	1	1	1	1	2
Patients	1	2	3	4	5	6	7	8
Age/Sex	61/M	74/M	52/F	36/M	70/F	69/M	84/F	46/M
Diagnosis	MPM	MPM	MPM	MPM	Ovarian Ca	MPM	MPM	MPM
MSLN 2+/3+ (% of tumor cells)	90	60	73	95	55	90	100	90
No. Prior Rx	8	3	3	9	6	5	2	9
Prior ICI	Yes	Yes	No	Yes	No	Yes	Yes	Yes
Prior anti-MSLN	Yes	No	No	No	No	Yes	No	Yes
Bridging Therapy	None	Pemetrexed/ Cisplatin	Pemetrexed/ Carboplatin	None	Liposomal doxorubicin	None	TIE2 inhibitor + Carboplatin	None
LD Chemo	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Gavo-cel dose	5x10 ⁷ /m ²	5x10 ⁷ /m ²	5x10 ⁷ /m ²	5x10 ⁷ /m ²	5x10 ⁷ /m ²	5x10 ⁷ /m ²	5x10 ⁷ /m ²	1x10 ⁸ /m ²
Best Target Lesion Response	SD	PR	PR	PR	PR	SD	SD	SD
Best RECIST v1.1 Response	SD	PR*	SD	PR	PR	SD	SD	SD

Data Cutoff – November 24, 2020



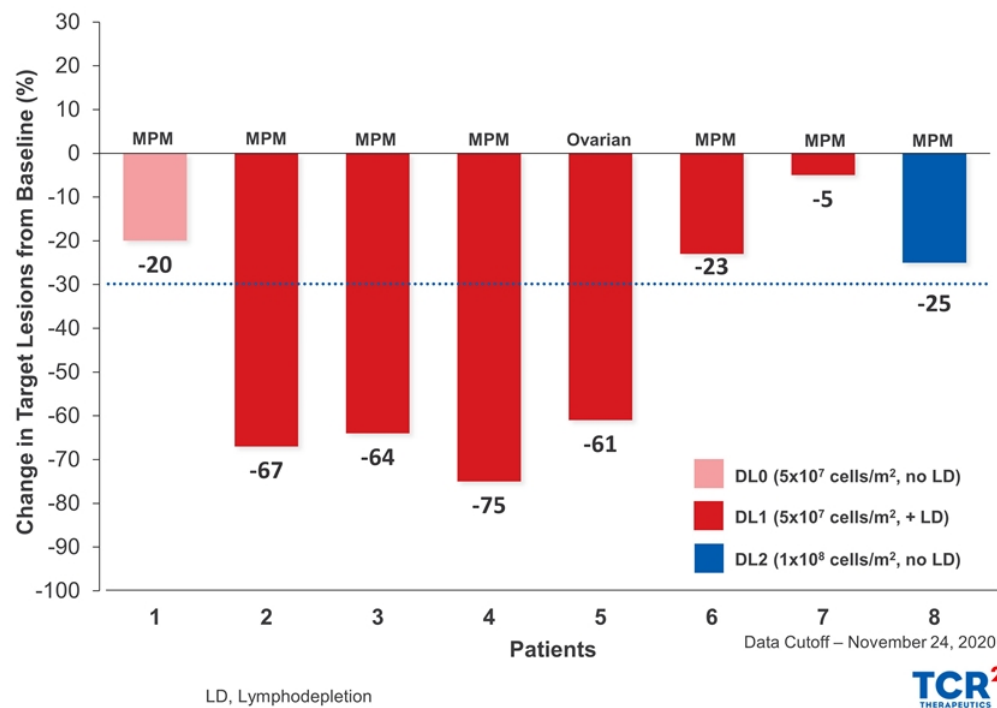
*Unconfirmed
ICI: immune checkpoint inhibitor

TCR²
THERAPEUTICS

Tumor Regression Observed in All Patients with Gavo-cel

Overall Response Rate 38%, Disease Control Rate 100%

Patients	All	Gavo-cel + LD
Number	8	6
ORR	38%	50%
DCR	100%	100%



Early Efficacy Case Study: Patient 5

Partial Response (RECIST v1.1), Tumor Regression (61%)

70-year-old female,

High grade, Stage IV serous ovarian cancer

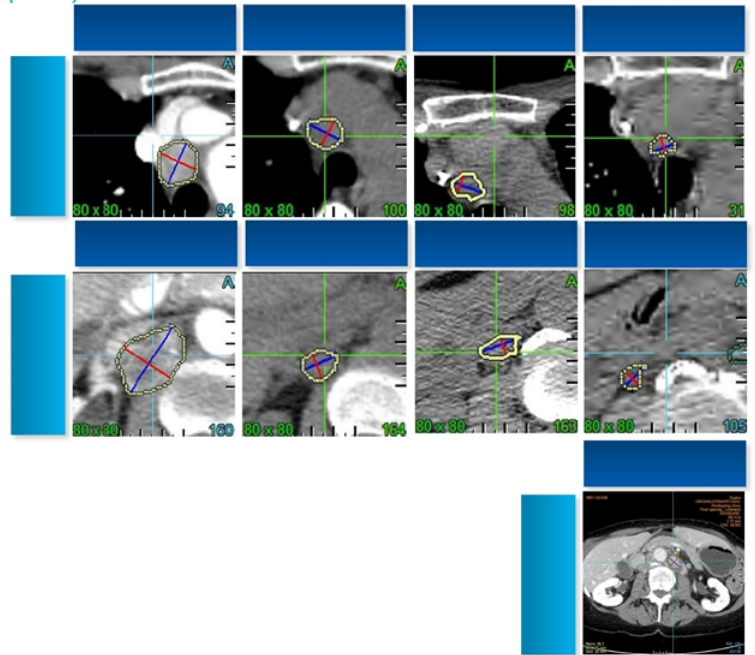
- *TP53*^{R248Q}, *CCNE1* amplified, wild type *BRCA1/2*
- Failed 6 prior lines of therapy
- Platinum resistant

Enrolled in Gavo-cel Clinical Trial Study

- **April 2020:** Lymphodepletion with Flu/Cy followed by gavo-cel at $5 \times 10^7/\text{m}^2$

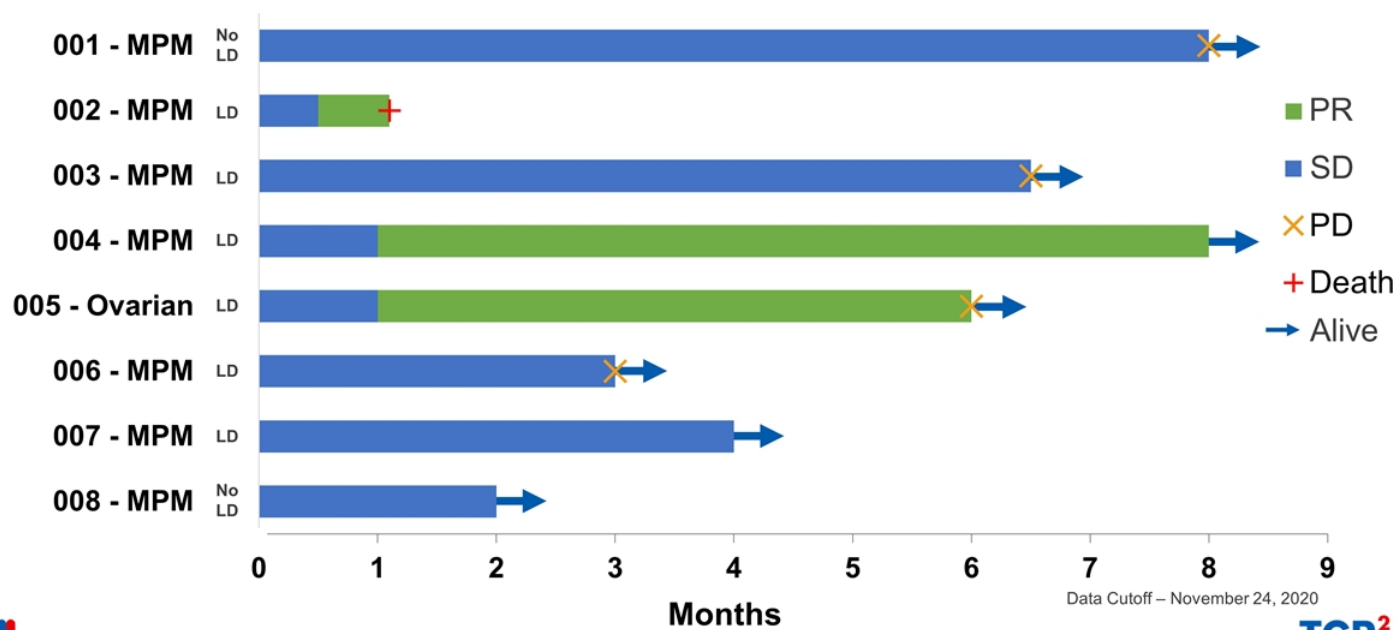
Response Post Gavo-cel

- Target Lesions: **PR (at months 1, 2, 3, 6)**
- Non-target Lesions: **CR (at months 1, 2, 3, 6)**
- Best overall assessment: **PR (at month 3)**
- Overall: **PD (new lymph node lesion)**

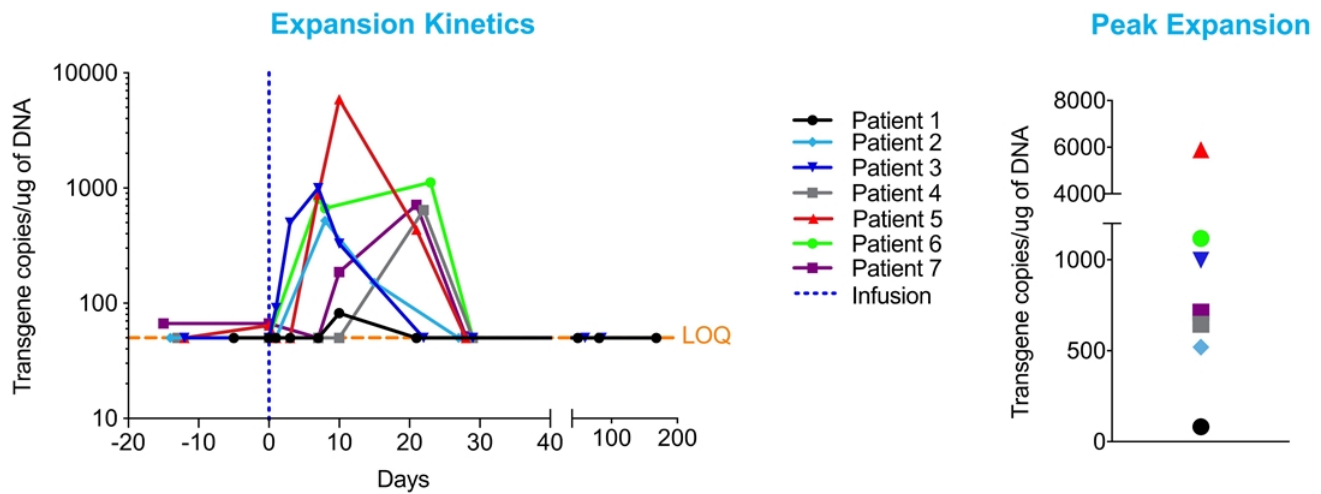


Patient Response and Follow-Up

Overall Response Rate 38%, Disease Control Rate 100%



Gavo-cel Expansion in Peripheral Blood by qPCR

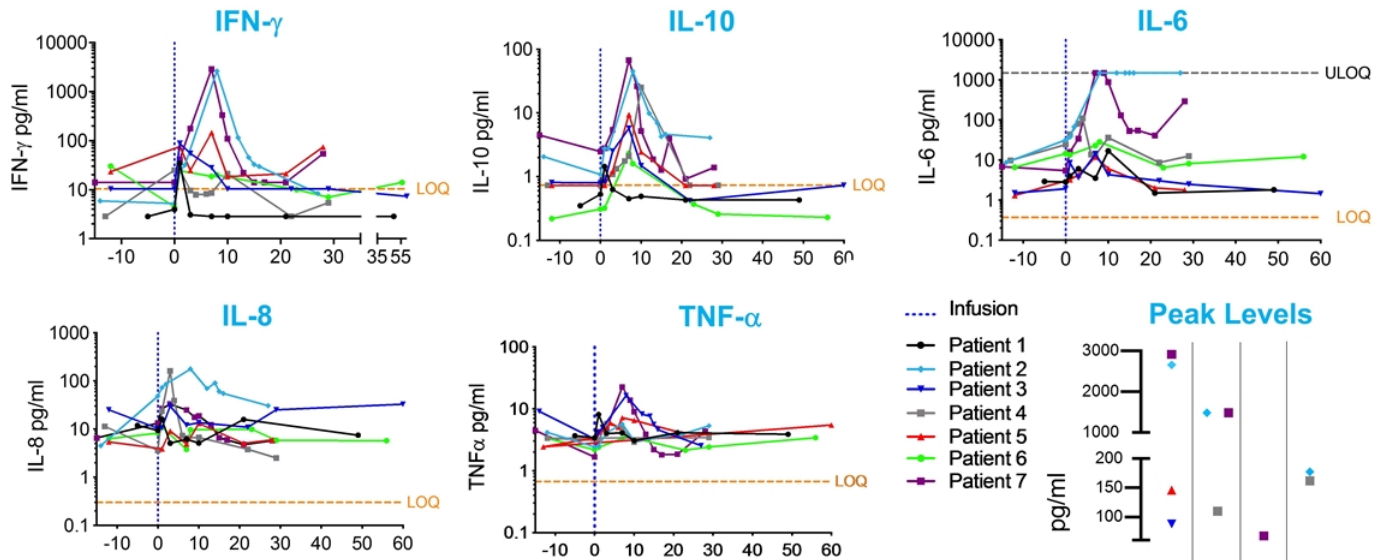


- Expansion observed in all patients
- Peak expansion occurred between days 7-23 post infusion
- Peak expansion higher with lymphodepletion

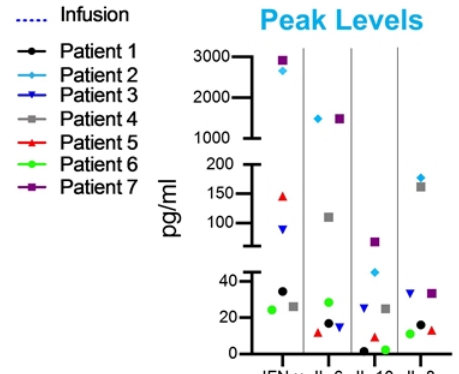


Data Cutoff – November 24, 2020

Increased Plasma Cytokines Following Gavo-cel Infusion



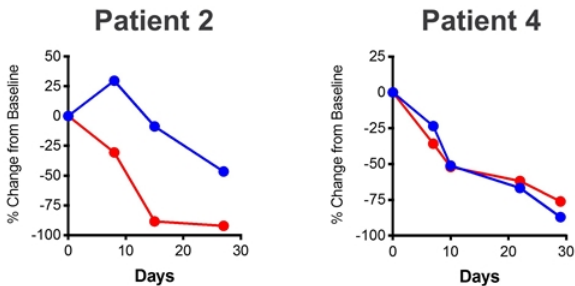
- Plasma cytokine levels increased in all patients
- Higher levels were observed in patients 2 and 7 (grade 3 CRS)



Data Cutoff – November 24, 2020

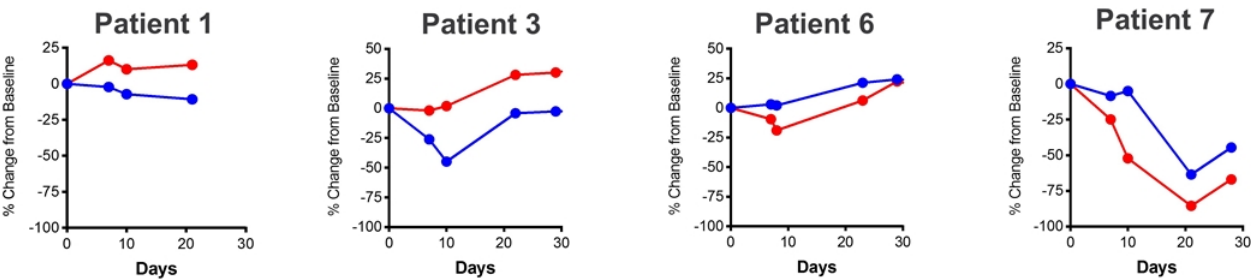
Potential Correlation Between Soluble Biomarkers & Response

Responders



Disease Response Biomarkers:
SMRP: soluble mesothelin related peptide
MPF: megakaryocyte potentiating factor

Stable Disease



Data Cutoff – November 24, 2020

Summary and Next Steps

Key Clinical Findings

- Tumor regression observed in every patient
- RECIST PR in ovarian cancer
- Manageable safety profile
- High rate of patient eligibility and 100% manufacturing success

Next Steps

- Accelerated dose escalation with new 14-day safety observation period in Phase 1
- Identification of RP2D
- Initiate Phase 2 expansion portion
 - Assessment of efficacy in four indications
 - Combination with anti-PD1 antibody
 - Option for retreatment

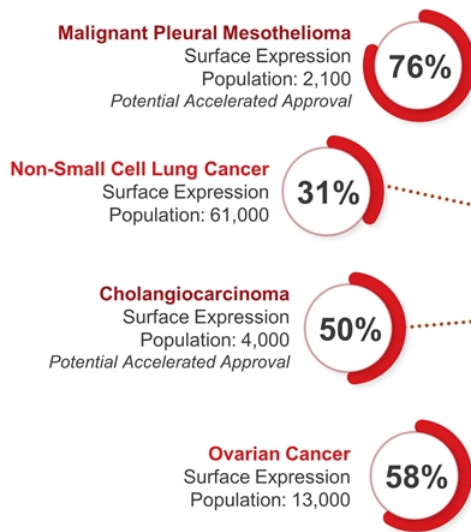


RP2D: Recommended Phase 2 Dose

Mesothelin Solid Tumors Represent A Significant Market

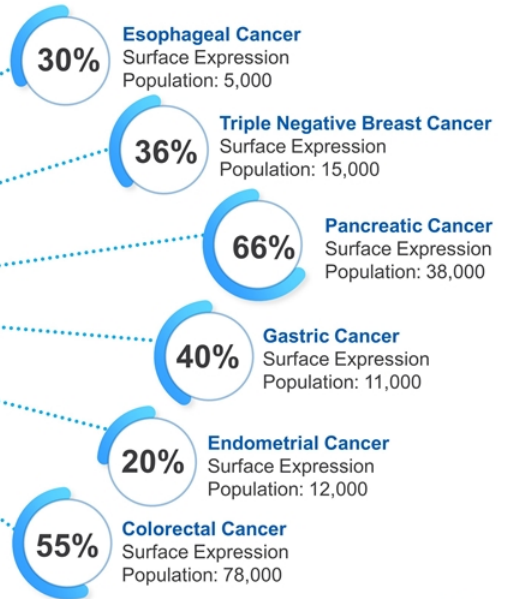
Initial Gavo-cel Indications

Population: 80,000 patients



Expansion Opportunities

Population: 159,000 patients



Percent of Patients with Mesothelin Surface Expression

Refs: Inaguma 2017, SEER Statistics, Morello 2016, Tozbikian 2014

Clinical Corporate Milestones

2020	Present Initial Phase 1 Data for Gavo-cel	✓
2020	Present Interim Phase 1 Update for Gavo-cel	✓
1H21	Present Interim Phase 1 Data for Gavo-cel at Medical Meetings	
2021	Announcement of RP2D for Gavo-cel	
2021	Initiation of Phase 2 Expansion for Gavo-cel	
2021	Present Initial Phase 1 Data for TC-110	
2021	IND Filing for Third TRuC Program	





POWERING THE TCR

TO TRANSFORM THE LIVES OF
CANCER PATIENTS WITH
SOLID TUMORS

Thank You

