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 Exchange Act of 1934

Date of Report (date of earliest event reported): October 5, 2020

IOVANCE BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	
(State of Incorporation)	
001-36860	**75-3254381**
Commission File Number	**(I.R.S. Employer Identification No.)**
999 Skyway Road, Suite 150 **San Carlos, California**	**94070**
(Address of Principal Executive Offices)	**(Zip Code)**

(650) 260-7120
(Registrant's Telephone Number, Including Area Code)

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 240.13e-4(c)).

Indicate by check mark whether the registrant is an emerging growth company as defined in 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. ☐

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, par value $0.000041666 per value	IOVA	The Nasdaq Stock Market, LLC

Item 8.01 Other Events.

On October 5, 2020, Iovance Biotherapeutics, Inc. (the "Company") updated its corporate presentation that it uses for presentations at healthcare conferences and to analysts, current stockholders, and others. A copy of the Company's presentation that it intends to use at such events is attached as Exhibit 99.1 and incorporated herein by reference.

On October 5, 2020, the Company issued a press release providing a regulatory update for its tumor-infiltrating lymphocyte therapy lifileucel in metastatic melanoma. The full text of the press release is attached hereto as Exhibit 99.2 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Iovance Biotherapeutics, Inc., Corporate Presentation – October 2020.
99.2	Press Release dated October 5, 2020.

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.

Date: October 5, 2020

IOVANCE BIOTHERAPEUTICS, INC.

By: /s/ MARIA FARDIS
Maria Fardis, Chief Executive Officer

IOVANCE BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY

Investigating the Power of Tumor Infiltrating Lymphocytes for Treatment of Cancer

October 2020

Forward Looking Statements

Certain matters discussed in this presentation are "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "us," or "our") within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). All such written or oral statements made in this presentation, filings with the Securities and Exchange Commission ("SEC"), reports to stockholders and in meetings with investors and analysts, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by the PSLRA. Without limiting the foregoing, we may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "forecast," "guidance," "outlook," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the success, timing, projected enrollment, manufacturing and production capabilities, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates (including both Company-sponsored and collaborator-sponsored trials in both the U.S. and Europe), such as statements regarding the timing of initiation and completion of these trials; the strength of the Company's product pipeline; and the guidance provided for the Company's future cash, cash equivalents, short term investment, restricted cash balances, and forecasted operating expenses. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements, including, without limitation, the following substantial known and unknown risks and uncertainties inherent in the Company's business: the COVID-19 pandemic may have an adverse effect on the Company and its clinical trials, including potential slower patient recruitment, inability of clinical trial sites to collect data, inability of the Company or its contract research organizations to monitor patients, as well as U.S. Food and Drug Administration ("FDA") availability due to competing priorities; our ability to achieve long-term profitability and successfully commercialize our products alone or with third parties, as well as our history of operating losses and our expectations that we will continue to incur significant operating losses; our limited operating history in our current line of business, which makes it difficult to evaluate our prospects, our business plan or the likelihood of our successfully implementing such business plan; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates (including, with respect to lifileucel for the treatment of metastatic melanoma, reaching agreement with the FDA on the appropriate potency assay and the timing to submit a biologics licensing application ("BLA") to the FDA), and our ability to successfully commercialize any product candidates for which we obtain FDA approval; our limited history in conducting clinical trials, on which our future profitability is substantially dependent, and our need to rely on third parties, including contract research organizations, contract manufacturing organizations and consultants, in connection with the conduct, supervision and monitoring of our clinical trials for our product candidates; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; the risk that a slower rate of enrollment may delay the Company's clinical trial timelines or otherwise adversely impact our clinical development activities; the risk that enrollment may need to be adjusted for the Company's trials and cohorts within those trials based on FDA and other regulatory agency input; the new version of the protocol which further defines the patient population to include more advanced patients in the Company's cervical cancer trial may have an adverse effect on the results reported to date; the risk that the results obtained in our ongoing clinical trials may not be indicative of results obtained in future clinical trials or that data within these trials may not be supportive of product approval, including that later developments with the FDA may be inconsistent with already completed FDA meetings; the risk that the FDA may not agree with our approach to expand our cervical cancer trial to include Cohort 2 of the C-145-04 trial; the risk that changes in patient populations may result in changes in preliminary clinical results; the Company's ability or inability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical, safety, manufacturing and control requirements; the risk that regulatory authorities may potentially delay the timing of FDA or other regulatory approval of, or other action with respect to, our product candidates, or that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA or other regulatory authorities; the risk that the Company's interpretation of the results of its clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; our ability to obtain and maintain intellectual property rights related to our product pipeline; our ability to successfully implement our research and development programs and collaborations; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability to obtain tax incentives and credits and the risk that our existing net operating loss carryforwards and research tax credits may expire or otherwise be limited in use; the success of our manufacturing, license or development agreements; risks related to the Company's ability to maintain and benefit from accelerated FDA review designations, including breakthrough therapy designation or regenerative medicine advanced therapy designation, which may not result in a faster development process or review of the Company's product candidates (and which may later be rescinded by the FDA), and which does not assure approval of such product candidates by the FDA or the ability of the Company to obtain FDA approval in time to benefit from commercial opportunities; the ability or inability of the Company to manufacture its therapies using third party manufacturers or its own facility may adversely affect the Company's potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in the Company's sponsored trials; our dependence on additional financing to fund our operations and complete the development and commercialization of our product candidates, and the risks that raising such additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidates; the risk that additional expenses may decrease our estimated cash balances and increase our estimated capital requirements; and other factors that may have a material adverse effect on the Company's business and clinical development, including general economic conditions, the Covid-19 pandemic and regulatory developments, not within the Company's control.

2020 Recent Updates

Data flow:

Updated Cohort 2 at ASCO

Early pivotal Cohort 4 data in melanoma by investigator

Data showing effect of Moffitt TIL in NSCLC presented at AACR 2020

> 90% manufacturing success rate in over 300 patients

FDA Type B Meeting held, Agreement on clinical follow up for Cohort 4 reached:

- 6 months from initial response by IRC
- Cohort 2 can be supportive

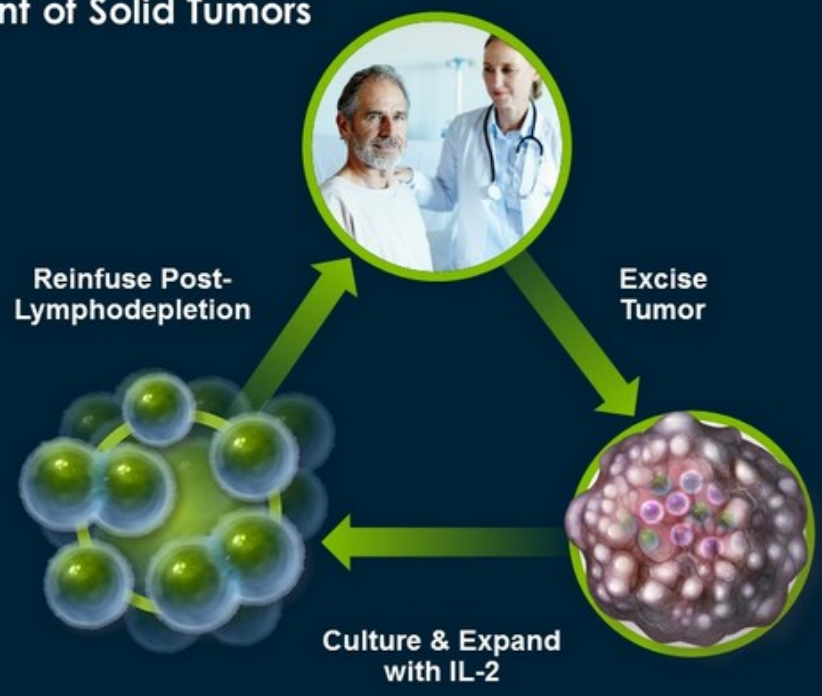
Additional work on potency assays will be pursued. Communication with FDA will continue.

IOVANCE

TIL: Leading Platform for Treatment of Solid Tumors

Tumor-Infiltrating Lymphocytes (TIL) – Unique Mechanism in Immuno-oncology

- Highly personalized therapy
- Our own immune system amplified and rejuvenated



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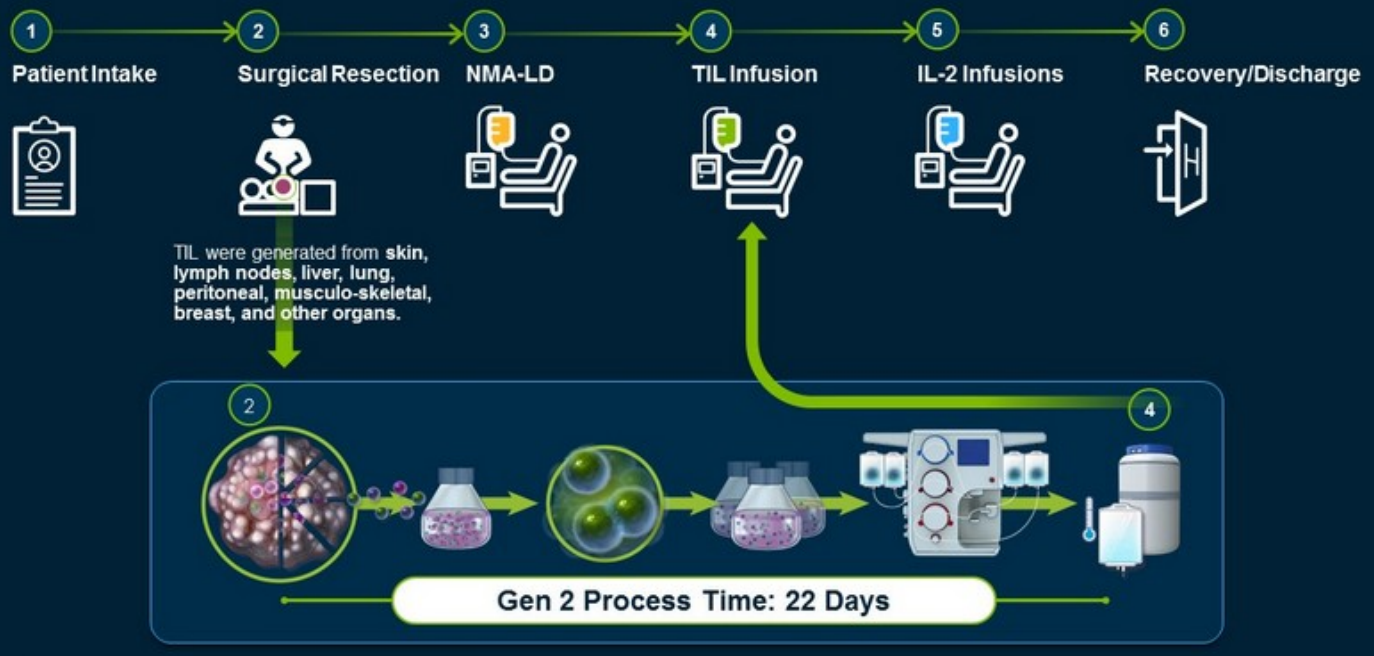
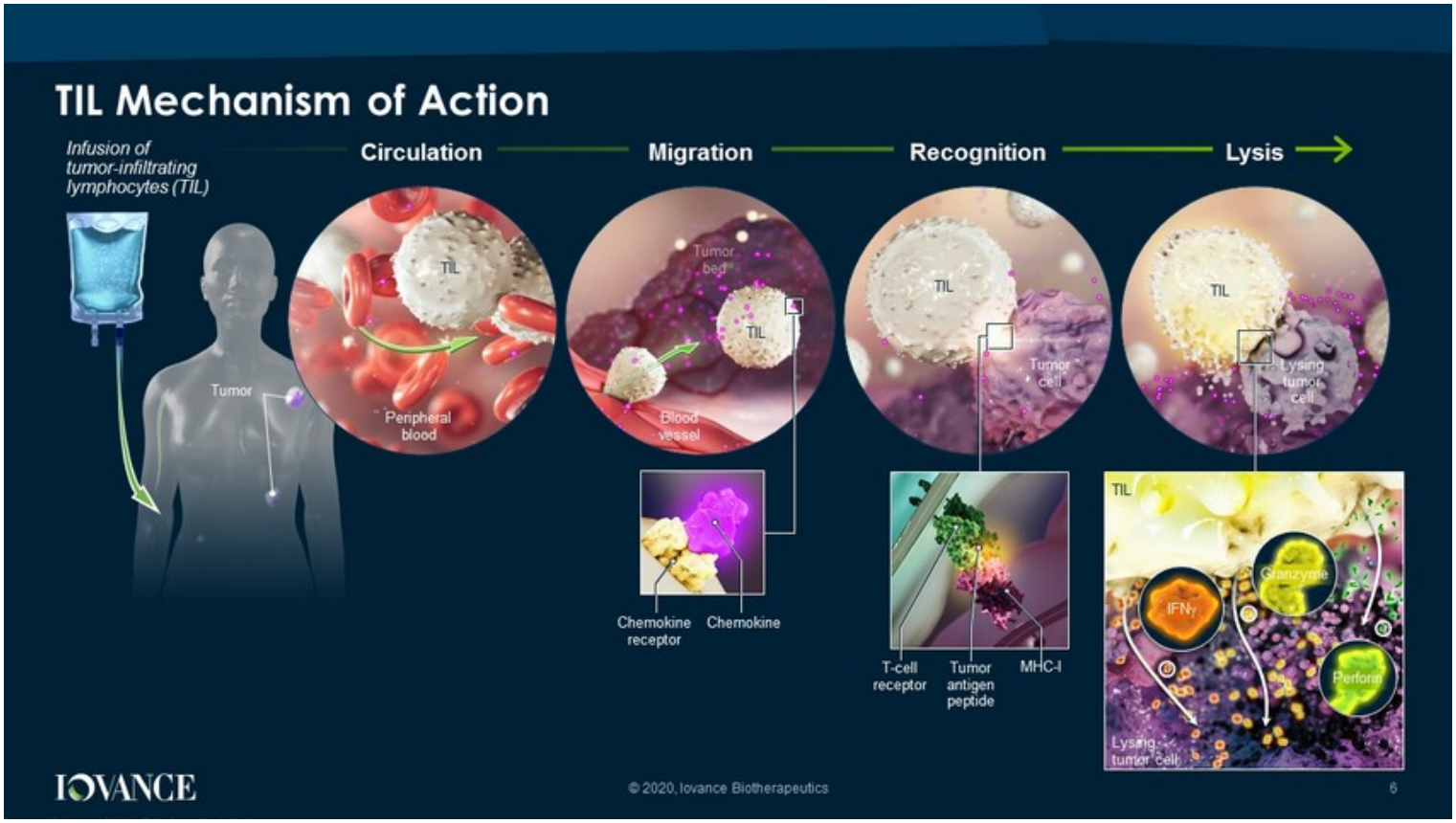
Iovance Proprietary Centralized, Scalable, and Efficient GMP Manufacturing




TIL Mechanism of Action
Infusion of tumor-infiltrating lymphocytes (TIL)
Circulation
Migration
Recognition
Lysis
Tumor
TIL
Peripheral blood
Tumor bed
Blood vessel
Chemokine receptor
Chemokine
T-cell receptor
Tumor antigen peptide
MHC-I
Tumor cell
Lysing tumor cell
IFNγ
Granzyme
Perforin
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Leveraging Tumor Infiltrating Lymphocyte (TIL) to Address Unmet Need

Discovery | **Manufacturing Development, Clinical Program Establishment** | **Pre-Commercialization**

2011

TIL therapy conducted by Steven Rosenberg/NCI published results showing: **56% ORR**[1] and **24% CR** rate in melanoma patients, with durable CRs as an early line therapy[2]

2015

FDA Orphan Drug Designation for lifileucel in malignant melanoma

2016

First patient dosed for Gen 1 lifileucel in melanoma

Gen 2 manufacturing developed and transferred to CMOs

2017

Head & Neck and Cervical studies began

FDA Fast Track designation for lifileucel in melanoma received

2018

FDA RMAT designation for lifileucel in advanced melanoma received

FDA EOP2 meeting for lifileucel held

Lifileucel Cohort 2 clinical data showed **38% ORR in 47 patients,** patients with average 3.3 prior lines of therapy

Two rounds of financing conducted: **over $425 mil raised**

2019

First patient dosed for melanoma registrational trial

FDA Fast Track, BTD in cervical

FDA EOP 2 held for lifileucel for cervical

File IND for PBL in chronic lymphocytic leukemia (CLL), IND cleared and first patient dosed

Clinical IRC **data from Cohort 2 of melanoma at SITC shows 35% ORR**

2020-2021

TIL manufactured by Moffitt shows **2 durable CRs** in post-PD1 NSCLC

Data presentation by investigator for: Cohort 2 at ASCO, early data in Cohort 4 pivotal melanoma

Complete enrollment for registrational program in cervical

Start a registration-directed NSCLC program

Hold pre-BLA meeting with FDA

Submit BLA for lifileucel

[1] Rosenberg, S. A., et al. *Clinical Cancer Research*, 2011, 17, 4550
[2] Goff, S. L. et al. *Journal of Clinical Oncology*, 2016, 34(20), 2389-2397

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Key Highlights for Melanoma Cohort 2 Data

2019: Melanoma Data update at SITC (8 Nov 2019)[1]

Melanoma Cohort 2 showed

36.4% ORR

by investigator and

34.8% ORR

as read by independent review committee (IRC) (N=66)

2020: Updated Melanoma Data cut

ASCO20

Median DOR not reached at 18.7 months of median study follow up

(investigator assessed) [2]

[1]Sarnaik et al., SITC 2019; P865
[2]Sarnaik et al., ASCO 2020; 10006

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Investment Highlights

Leading cell therapy company focused on treatment of solid tumors

Large market opportunity and strong unmet need

- Initial focus in post-checkpoint solid tumors
- Expansion into combinations and earlier lines of therapy
- Five company-sponsored programs in melanoma, cervical, head & neck, non-small cell lung cancer (NSCLC), and CLL indications

Potential to be the first cell therapy approved for solid tumors in melanoma and cervical

- Accelerated path to approval in melanoma and cervical cancer
- Last patient dosed in pivotal trial for melanoma
- BLA filings expected 2021
- Melanoma: RMAT, Orphan Drug, and Fast Track
- Cervical: BTD, Orphan Drug and Fast Track

Efficient and scalable proprietary manufacturing

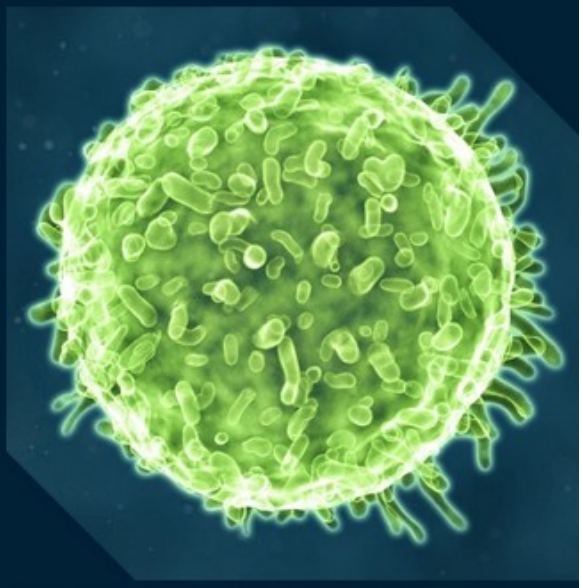
- U.S. and E.U. capacity with contract manufacturers
- Building Iovance 136,000 sq. ft. manufacturing facility in Philadelphia
- Rapid 22-day Gen 2 manufacturing with 90%+ success rate
- **300+ patients treated with Iovance proprietary process**

Broad platform and wide applications explored through partnerships

- Investigator-led programs to evaluate additional solid tumors or new combinations
- Data from Moffitt TIL in NSCLC as a new indication for Iovance
- Touch points with institutions including NIH/NCI, Moffitt Cancer Center, MD Anderson, Yale, and University of Montreal (CHUM)

Highly Individualized, Specific & Potent Attack Against Cancer

Leverages and enhances the body's natural defense against cancer using a patient's own Tumor Infiltrating Lymphocytes, or TIL



- **Polyclonal:** Can recognize multiple neoantigens
  - Effective in heterogeneous solid tumors
  - Data in melanoma, cervical, head & neck, and lung cancers
- **Individualized:** TIL of each patient is specific and private with little overlap of uCDR3 between patients[1]
- **Persistence:** 100% of patients had TIL persisting at Day 42[1]
- **Immunological memory:** No additional maintenance therapy after infusion
  - Responses in treatment naïve and refractory melanoma; including checkpoint refractory
  - Durable complete responses in cervical cancer patients, maintained at 53 and 67 months[2]
  - Durable CRs observed in NSCLC patients beyond one-year post-TIL[3]

[1] Gontcharova, et al., Persistence of cryopreserved tumor-infiltrating lymphocyte product lifileucel (LN-144) in C-144-01 study of advanced metastatic melanoma, AACR 2019, Abstract #LB-069
[2] Stevanovic, et al., Treatment of Metastatic Human Papillomavirus-Associated Epithelial Cancers with Adoptive Transfer of Tumor-Infiltrating T Cells, ASCO 2018, Abstract #3004
[3] Creelan, et al., Durable complete responses to adoptive cell transfer using tumor infiltrating lymphocytes (TIL) in non-small cell lung cancer (NSCLC): a phase I trial, AACR 2020, Abstract #20-LB-10617

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Competitive Advantages of TIL in Solid Tumors

Checkpoints	TCR	CAR-T (Liquid tumors)	TIL (Solid tumors)
Target multiple tumor antigens	Target only single tumor antigen	Mainly target only single/ surface tumor antigen	**Target multiple tumor antigens**
Long maintenance period	One-time treatment	One-time treatment	**One-time treatment**
Utility in several solid tumors	Few solid tumors treated so far	No examples of successful utility in solid tumors	**Available data in: melanoma, cervical, head & neck, and lung cancers**
Potential long-term irreversible toxicities	Potential on-target, off-tissue effects	Potentially immunogenic: cytokine release syndrome	**No unexpected off-tissue effects found to date**
Off-the-shelf	Autologous	Autologous	**Autologous**

TIL target a diverse array of cancer antigens; we believe this approach represents a **highly differentiated, customized, and targeted immunotherapy**

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Broad, Iovance-Owned IP Around TIL Therapy

Manufacturing

Twelve granted U.S. patents for compositions and methods of treatment in a broad range of cancers relating to Gen 2 manufacturing process including combinations with PD-1 antibodies

Advanced Technologies

Patent applications filed for a wide range of TIL technologies including:

- Marrow infiltrating (MIL) and peripheral blood lymphocyte therapies (PBL)
- Novel manufacturing processes including selected TIL process
- Use of costimulatory molecules in TIL therapy
- Stable and transient genetically-modified TIL therapies
- Patient subpopulations for TIL therapies

Iovance Cell Therapy Center (*i*CTC)

- Build-to-suit custom facility located in the Navy Yard, Philadelphia, PA
- ~136,000 sq. feet, $85 mil investment
- Clean room build initiated April 2020
- Commercial GMP production is expected to commence in 2022
- Significant reduction in COGS expected

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Significant Market Potential in Solid Tumors

90%
of all cancer cases are solid tumors

1.6M
New cases of solid tumors in the U.S.[1]

Move into earlier line of therapy

Expand into other indications

Solid Tumor Indication	Deaths[1]	New Cases[1]
Melanoma	7,230	96,480
Cervix Uteri	4,250	13,170
Lung & Bronchus	142,670	228,150
Oral Cavity, Pharynx & Larynx	10,860	53,000
Breast	41,760	268,600
Pancreatic	45,750	56,770
Brain & Other Nervous System	17,760	23,820
	Potential to address unmet need in late lines of treatment	Potential market for early lines in combo with standard of care

[1] https://seer.cancer.gov

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Current Clinical Pipeline and Select Collaboration Studies

	Regimen	Trial	Indication	N	Partner	Phase 1	Phase 2	Pivotal
Company sponsored studies	Lifileucel	C-144-01	Melanoma	178	—			
	Lifileucel	C-145-04	Cervical cancer	138	—			
	LN-145/ LN-145-S1	C-145-03	Head & neck cancer	55	—			
	Lifileucel + pembrolizumab LN-145-S1 LN-145 + pembrolizumab LN-145 + pembrolizumab LN-145	IOV-COM-202	Melanoma Melanoma Head & neck Non-small cell lung Non-small cell lung	~75	—			
	IOV-2001	IOV-CLL-01	Chronic lymphocytic leukemia	~70	—			
Select investigator sponsored proof-of-concept studies	MDA TIL	NCT03610490	Ovarian, colorectal, pancreatic	~54	MD Anderson Cancer Network			
	LN-145	NCT03449108	Ovarian, sarcomas	~54	MD Anderson Cancer Network			
	Moffitt TIL + nivolumab	NCT03215810	Non-small cell lung	20	MOFFITT CANCER CENTER			

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Metastatic Melanoma

Potential Market for Metastatic Melanoma

- Estimated 7,230[1] U.S. patient deaths due to melanoma
- Limited options after progression on checkpoint and BRAF/MEK inhibitors

> *"Nature has selected TIL to recognize features unique to the tumor not present on normal tissues, which helps make a TIL therapy approach effective compared to other cell therapy strategies for solid tumors. Iovance TIL treatment has a novel mechanism of action, completely separate from those of other treatment options, and has resulted in highly durable responses in patients that have progressed on prior FDA-approved treatment for their metastatic melanoma."*
>
> — Dr. Amod Sarnaik
> Department of Cutaneous Oncology, the Immunology Program and the Melanoma Center of Excellence at Moffitt Cancer Center

Metastatic Melanoma Facts

309k	**New Cases WW** each year[3]	**62k**	**Deaths WW** each year[3]
96k	**Diagnoses in U.S.** each year[1]	**7k**	**Deaths in U.S.** each year[1]

1st line: **Immuno -therapy**	BRAF/MEK inhibitors for **BRAF positive**	**Chemotherapy ORR 4-10%**[2] **OS ~7-8 mons**[4]

(1) in 2019, https://seer.cancer.gov;
(2) CheckMate-37 Trial Results (ICC 10%), Keytruda label (4%);
(3) *JAMA Oncol.* 2019; 5(12):1749-1768. doi:10.1001/jamaoncol.2019.2996;
(4) *Eur J Cancer.* 2016; 65:182-184. *J Clin Oncol.* 2018; 36 (suppl: abstr e21588)

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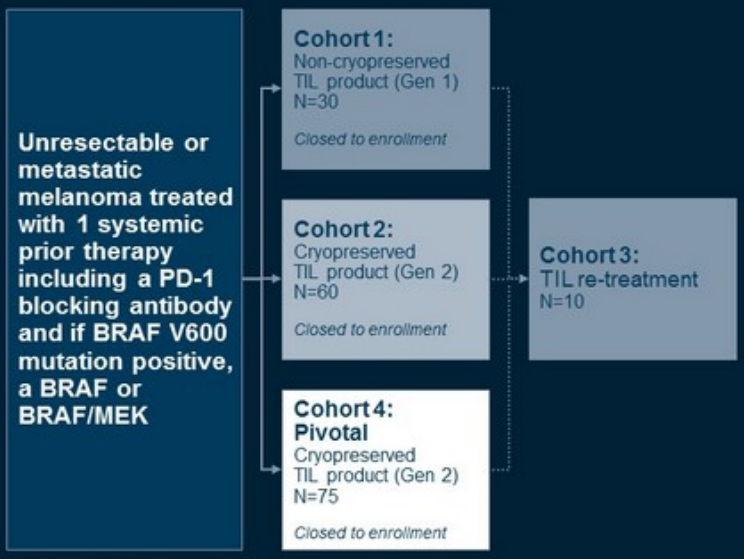
C-144-01: Phase 2 Study Design

Phase 2, multicenter study to assess the efficacy and safety of autologous Tumor Infiltrating Lymphocytes (lifileucel) for treatment of patients with metastatic melanoma (NCT02360579)



Endpoints

- Primary: Efficacy defined as IRC ORR

Study Updates

- Mar 2019: Cohort 4 (pivotal trial) FPI
- Jun 2019: Full Cohort 2 data on 66 patients presented at ASCO
- Nov 2019: IRC Cohort 2 data presented at SITC
- Nov 2019: Investigator read of Cohort 2 sub-analysis for primary refractory to PD-1 presented
- Jan 2020: last patient dosed
- May 2020: Cohort 4 early data show 32.4% ORR at 5.3 months of median study follow up
- May 2020 ASCO oral: Cohort 2 median DOR not reached at 18.7 months of median study follow up

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C-144-01: Cohort 2 Patient Characteristics at ASCO 2020

CHARACTERISTIC	Cohort 2, N=66, (%)
Gender, n (%)	
Female	27 (41)
Male	39 (59)
Age, years	
Median	55
Min, Max	20, 79
Prior therapies, n (%)	
Mean # prior therapies	3.3
Anti-PD-1	66 (100)
Anti-CTLA-4	53 (80)
BRAF/MEK	15 (23)
Progressive Disease for at least 1 prior therapy	
Anti-PD-1	65 (99)
Anti-CTLA-4	41 (77[1])
Baseline ECOG score, n (%)	
0	37 (56)
1	29 (44)

CHARACTERISTIC	Cohort 2, N=66, (%)
BRAF Status, n (%)	
Mutated V600	17 (26)
Wild Type	45 (68)
Unknown	3 (5)
Other	1 (2)
Baseline LDH (U/L)	
Median	244
1-2 times ULN	19 (29)
> 2 times ULN	8 (12)
Target Lesions Sum of Diameter (mm)	
Mean (SD)	106 (71)
Min, Max	11, 343
Number of Target and Non-Target Lesions (at Baseline)	
>3	51 (77)
Mean (SD)	6 (2.7)
Patients with Baseline Liver and/or Brain Lesions	28 (42)

Cohort 2 patients have:

- 3.3 mean prior therapies, ranging from 1-9
- High tumor burden at baseline: 106 mm mean sum of diameters of the target lesions

[1]The denominator is the 53 patients who received prior anti-CTLA-4

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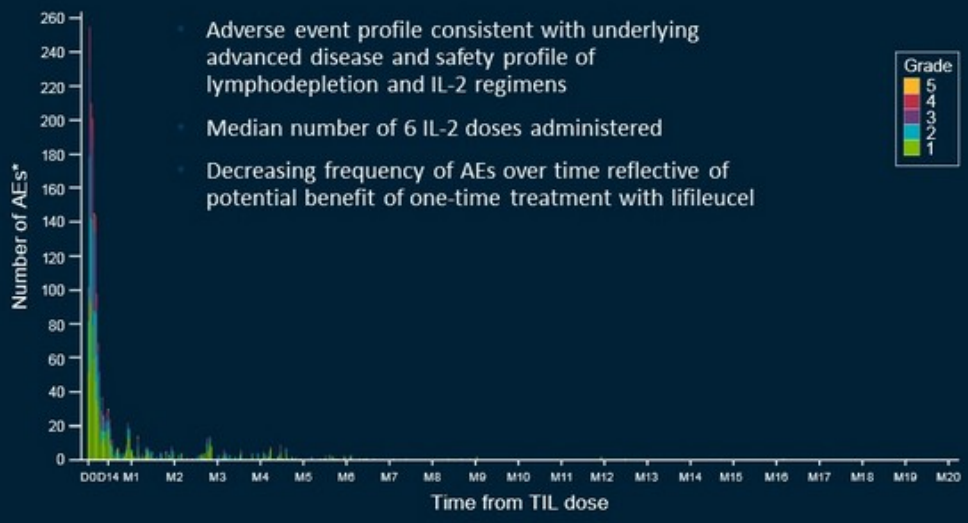
Adverse Events Tend to be Expected, Early and Transient

Frequency of AEs over time is reflective of potential benefit of one-time treatment with lifileucel



- Adverse event profile consistent with underlying advanced disease and safety profile of lymphodepletion and IL-2 regimens
- Median number of 6 IL-2 doses administered
- Decreasing frequency of AEs over time reflective of potential benefit of one-time treatment with lifileucel

Treatment Emergent Adverse Events (≥ 30%)

	Cohort 2 (N=66)		
Preferred term	Any Grade, n (%)	Grade 3/4, n (%)	Grade 5, n (%)
Number of patients reporting at least one Treatment-Emergent AE	66 (100)	64 (97.0)	2 (3.0)
Thrombocytopenia	59 (89.4)	54 (81.8)	0
Chills	53 (80.3)	4 (6.1)	0
Anemia	45 (68.2)	37 (56.1)	0
Pyrexia	39 (59.1)	11 (16.7)	0
Neutropenia	37 (56.1)	26 (39.4)	0
Febrile neutropenia	36 (54.5)	36 (54.5)	0
Hypophosphatemia	30 (45.5)	23 (34.8)	0
Leukopenia	28 (42.4)	23 (34.8)	0
Fatigue	26 (39.4)	1 (1.5)	0
Hypotension	24 (36.4)	7 (10.6)	0
Lymphopenia	23 (34.8)	21 (31.8)	0
Tachycardia	23 (34.8)	1 (1.5)	0

*The number of AEs is cumulative and represent the total number of patients dosed
Treatment-Emergent Adverse Events refer to all AEs starting on or after the first dose date of TIL up to 30 days. Patients with multiple events for a given preferred term are counted only once using the maximum grade under each preferred term. Safety terms which describe the same medical condition were combined.

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Potentially Efficacious Treatment for Patients with Limited Options

In heavily pretreated metastatic melanoma patients (3.3 mean prior therapies)

- **ORR 36%**
- **DCR 80%**
- ***Median DOR has not been reached at 18.7 mons of study follow up***
- Mean TIL cells infused: 27.3 x 10^9
- Median number of IL-2 doses: 5.5

Response	Patients, N=66 n (%)
Objective Response Rate	**24 (36.4)**
Complete Response	2 (3.0)
Partial Response	22 (33.3)
Stable Disease	29 (43.9)
Progressive Disease	9 (13.6)
Non-Evaluable(1)	4 (6.1)
Disease Control Rate	53 (80.3)
Median Duration of Response	**Not Reached**
Min, Max (months)	2.2, 26.9+

18% attrition in patients harvested (6% manufacturing failure)

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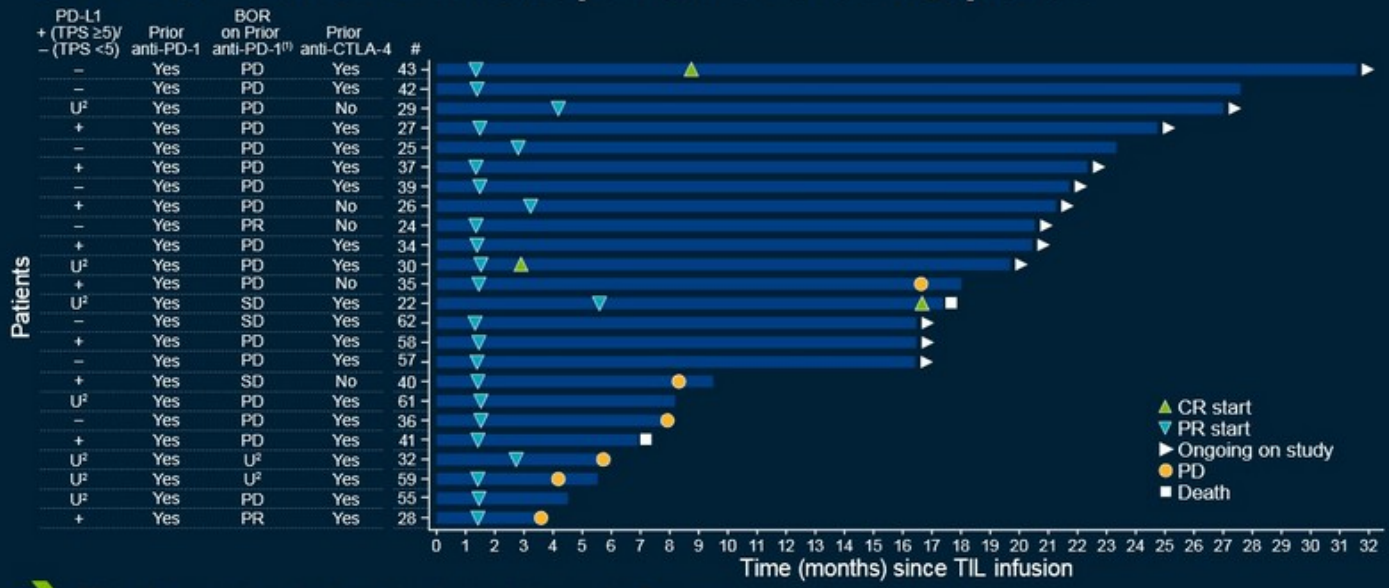
C-144-01 Cohort 2 Efficacy: Best Overall Response



79% of responders had received prior ipilimumab. Responses deepen over time.

(1) BOR is best overall response on prior anti-PD-1 immunotherapy. (2) U: unknown. (3) Patient 22 BOR is PR.

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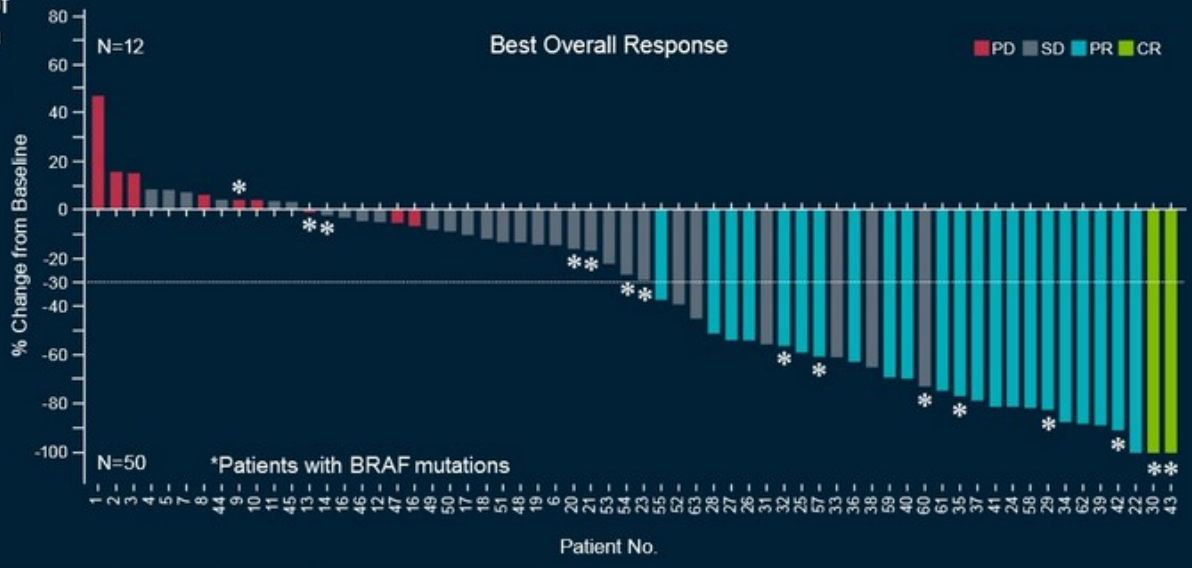
C-144-01 Cohort 2 Efficacy: Best Overall Response

- 81% (50/62) of patients had a reduction in tumor burden

- Mean Time to response 1.9 months (range 1.3-5.6)
- Responses are deep – nearly all responders are >30%



Three subjects had no post TIL disease assessment due to early death, and one due to start of new anti-cancer therapy.

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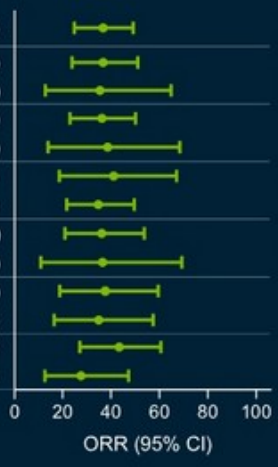
C-144-01 Cohort 2 ORR By Subgroup

Subgroup		n/N	ORR	95% CI
Overall		24/66	36.4	(24.9, 49.1)
Age Group	<65	19/52	36.5	(23.6, 51.0)
	≥65	5/14	35.7	(12.8, 64.9)
Prior Anti-CTLA-4 Use	Yes	19/53	35.8	(23.1, 50.2)
	No	5/13	38.5	(13.9, 68.4)
BRAF Mutation Status	V600 or V600K Mutated	7/17	41.2	(18.4, 67.1)
	Non-mutated	17/49	34.7	(21.7, 49.6)
PD-L1 Status (TPS ≥1% vs <1%)	≥1%	13/36	36.1	(20.8, 53.8)
	<1%	4/11	36.4	(10.9, 69.2)
PD-L1 Status (TPS ≥5% vs <5%)	≥5%	9/24	37.5	(18.8, 59.4)
	<5%	8/23	34.8	(16.4, 57.3)
Baseline ECOG	0	16/37	43.2	(27.1, 60.5)
	≥1	8/29	27.6	(12.7, 47.2)



Responses were demonstrated:

- Across a wide age range
- Even in patients who have progressed on prior anti-CTLA-4 or prior BRAF
- Regardless of the BRAF mutational status
- Equally in patients with PD-L1 low or high levels

CI, Confidence interval.
95% CI is calculated using the Clopper-Pearson Exact test.

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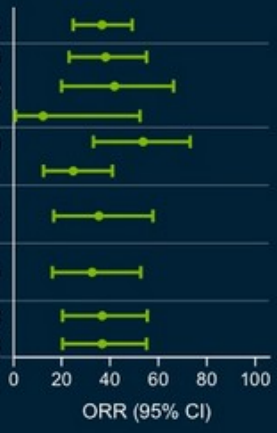
C-144-01 Cohort 2 ORR By Subgroup

Subgroup		n/N	ORR	95% CI
Overall		24/66	36.4	(24.9, 49.1)
Baseline Lactate Dehydrogenase	≤ ULN	15/39	38.5	(23.4, 55.4)
	1-2 x ULN	8/19	42.1	(20.3, 66.5)
	>2 x ULN	1/8	12.5	(0.3, 52.7)
Baseline Target Lesion Sum of Diameters	<70 mm	14/26	53.8	(33.4, 73.4)
	≥70 mm	10/40	25.0	(12.7, 41.2)
Patients with Baseline Liver Lesion		8/23	34.8	(16.4, 57.3)
Patients with Baseline Brain and/or Liver Lesion		9/28	32.1	(15.9, 52.4)
Time from Stop of Anti-PD-1/ PD-L1 to TIL Infustion	≤ median (4.76 months)	12/33	36.4	(20.4, 54.9)
	> median (4.76 months)	12/33	36.4	(20.4, 54.9)



Responses were demonstrated:

- In patients with elevated LDH (1-2x)
- In patients with bulky disease at baseline
- Patients with lesions in liver and/or brain
- Patients post anti-PD-1 regardless of duration of time from the patient's last anti-PD-1/L1

ULN, Upper Limit Normal; CI, Confidence interval.
95% CI is calculated using the Clopper-Pearson Exact test.

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C-144-01 Cohort 2: Conclusions

- In heavily pretreated metastatic melanoma patients with high baseline disease burden who progressed on multiple prior therapies, including anti-PD-1 and BRAF/MEK inhibitors, if BRAFV600 mutant, lifileucel treatment results in:
  - 36.4% ORR
  - 80.3% DCR
  - Median DOR was still not reached at 18.7 months of median study follow up
- Responses deepen over time

› Lifileucel has demonstrated potential efficacy and durability of response for patients with metastatic melanoma regardless of prior therapy with immune checkpoint therapies, or BRAF status

Late Stage (2L/3L) Melanoma Treatment Development Efforts

2L/3L melanoma treatment has no current standard of care

	Agent	ORR % (N)	Current Development Status	Prior Lines of Tx	Patient Characteristics
Combination with Anti-PD-1	**Checkpoints**				
	LAG-3 + nivo (BMS)	12% (N=61)[1]	Multiple 1L studies	1+	All comers, ECOG ≤2 • LAG-3 expression ≥1% (N=33) ORR=18%; • LAG-3 expression <1% (N=22) ORR=5%
	TLR9 agonists, HDAC, kinase inh				
	IMO-2125 (Idera) + ipi	22% (N=62)[2]	Phase 3, post-PD-1 melanoma ILLUMINATE 204	1-3	ECOG ≤1, intratumoral injection Median DOR was 11.4 months, mOS 10.1 months
	CMP-001 (CheckMate) + pembro	25% (N=82)[3]	Phase 1b	1+	ECOG ≤1, intratumoral injection
	Lenvatinib + pembro	21.4% (N=103)[4]	Phase 2	1+	Median DOR: 6.3 months mOS: 13.9 months
	Entinostat (Syndax) + pembro	19% (N=53)[5]	ENCORE 601	1+	ECOG ≤1
Single Agent	**Checkpoints**				
	TIGIT, TIM-3	Unknown	Phase 1/2		
	Cytokines				
	HD IL-2	8% (N=9)[6]		1+	HD IL-2 post anti-PD1
	Other				
	TIL	**36.4% (N=66)[7]**	**Phase 2, Cohort 2**	**3.3**	**All post anti-PD1**

[1] Asciert P et al., ESMO 2017; [2] Diab, et al., ESMO 2020; [3] Milhem M et al., SITC 2019; [4] Fernandez et al., ESMO 2020, LBA44; [5] Ramalingam et al., AACR 2019; [6] Buchbinder EI et al., JCO 2017; [7] Sarnaik et al., SITC 2019

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Cervical Cancer

Potential Market for Cervical Cancer

> *"TIL immunotherapy with lifileucel is literally redefining what is treatable and potentially curable in advanced metastatic chemo-refractory cervical cancer. Patients who only two years ago would be facing hospice as their only alternative now have access to this potentially life extending new treatment. This is the most exciting news in this field in decades."*

— Amir Jazaeri, M.D.
Director of the Gynecologic Cancer Immunotherapy Program in the Department of Gynecologic Oncology and Reproductive Medicine at MD Anderson

Cervical Cancer Facts

601k New Cases WW each year[1]

260k Deaths WW each year[1]

13k Diagnoses in U.S. each year[2]

4k Deaths in U.S. each year[2]

Available care:
Chemo -therapy
as first line option

For PD-L1 + patients, post-chemo receiving Keytruda[3]
ORR 14.3%

Available Care
for chemotherapy in 2L metastatic cervical patients
4.5-13%[4][5]

[1] JAMA Oncol. 2019;5(12):1749-1768. doi:10.1001/jamaoncol.2019.2996;
[2] https://seer.cancer.gov/
[3] https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf
[4] Schilder et al., Gynecologic Oncology 2005;
[5] Weiss, et al., A phase II trial of carboplatin for recurrent or metastatic squamous carcinoma of the uterine cervix: A Southwest Oncology Group Study

C-145-04: Pivotal Phase 2 Trial in Cervical Cancer

Phase 2, multicenter study to evaluate the efficacy and safety of autologous TIL (lifileucel, formerly LN-145) in patients with recurrent, metastatic or persistent cervical carcinoma (NCT03108495)

Endpoints

- Primary: ORR as determined by IRC
- Secondary: safety and efficacy

Study Updates

- March 2019: Fast Track designation
- May 2019: Breakthrough Therapy Designation
- June 2019: ASCO data presentation
- June 2019: FDA EOP2 held-existing study may be sufficient to support registration of lifileucel
- July 2019: Study expanded to enroll a total of 75 patients
- November 2019: Additional cohorts added (Cohorts 2-5)

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Lifileucel in Cervical Cancer Interim Update at ASCO 2019

Key Inclusion Criteria

- Recurrent, metastatic or persistent cervical carcinoma with at least 1 prior therapy
- Age ≥ 18

Endpoints

- Primary: efficacy defined as ORR by IRC per RECIST 1.1
- Secondary: safety and efficacy

Study Updates

- Fast Track and BTD received
- EOP2 meeting held with FDA

Baseline Demographics	N=27 (%)
Prior therapies	
Mean # prior therapies	2.4
Platinum-based	27 (100)
Taxane	26 (96)
Anti-VEGF	22 (82)
PD-1/PD-L-1	4 (15%)
Target lesions sum of diameter (mm)	
Mean (SD)	61 (38)
Min, Max	10, 165
Histologic Cell Type, n (%)	
Squamous Cell Carcinoma	12 (44)
Adenocarcinoma	12 (44)
Adenosquamous Carcinoma	3 (11)
Number of target & non-target lesions (at baseline)	
>3	17 (63)
Mean (min,max)	4 (1,9)

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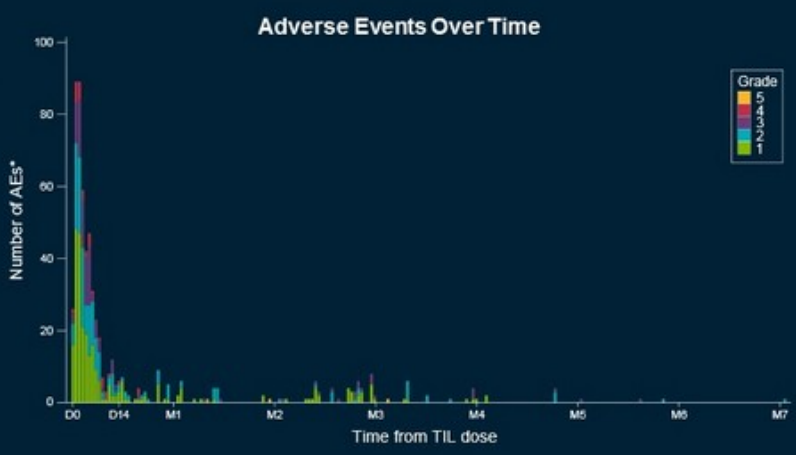
Adverse Events Tend to be Early and Transient

Frequency of AEs over time is reflective of potential benefit of one-time treatment with TIL (lifileucel)

Preferred Term	N=27 Any Grade, n (%)	Grade 3/4, n (%)	Grade 5, n (%)
Number of patients reporting at least one Treatment-Emergent AE**	**27 (100)**	**26 (96.3)**	**0**
Chills	21 (77.8)	0	0
Anemia	15 (55.6)	15 (55.6)	0
Diarrhea	14 (51.9)	2 (7.4)	0
Pyrexia	14 (51.9)	1 (3.7)	0
Thrombocytopenia	14 (51.9)	12 (44.4)	0
Neutropenia	11 (40.7)	8 (29.6)	0
Vomiting	11 (40.7)	1 (3.7)	0
Hypotension	10 (37.0)	4 (14.8)	0
Dyspnea	9 (33.3)	1 (3.7)	0
Febrile neutropenia	9 (33.3)	8 (29.6)	0
Hypoxia	9 (33.3)	3 (11.1)	0
Leukopenia	9 (33.3)	6 (22.2)	0
Hypomagnesemia	8 (29.6)	0	0
Sinus tachycardia	8 (29.6)	0	0



*The number of AEs is cumulative and represent the total number of patients dosed
Treatment-Emergent Adverse Events refer to all AEs starting on or after the first dose date of TIL up to 30 days. Patients with multiple events for a given preferred term are counted only once using the maximum grade under each preferred term. Safety terms which describe the same medical condition were combined.

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Significant Response Observed in Patients with Limited Options

In heavily pretreated cervical cancer patients (2.4 mean prior therapies)

- **CR 11%**
- **ORR 44%**
- **DCR 85%**
- **Median DOR has not been reached**
  - Median follow-up 7.4 months
- Mean TIL cells infused: **28×10^9**
- Median number of IL-2 doses: 6.0

Responses	N=27 (%)
Objective Response Rate	**12 (44%)**
Complete Response	3 (11%)
Partial Response	9 (33%)
Stable Disease	11 (41%)
Progressive Disease	4 (15%)
Non-Evaluable	0
Disease Control Rate	23 (85%)

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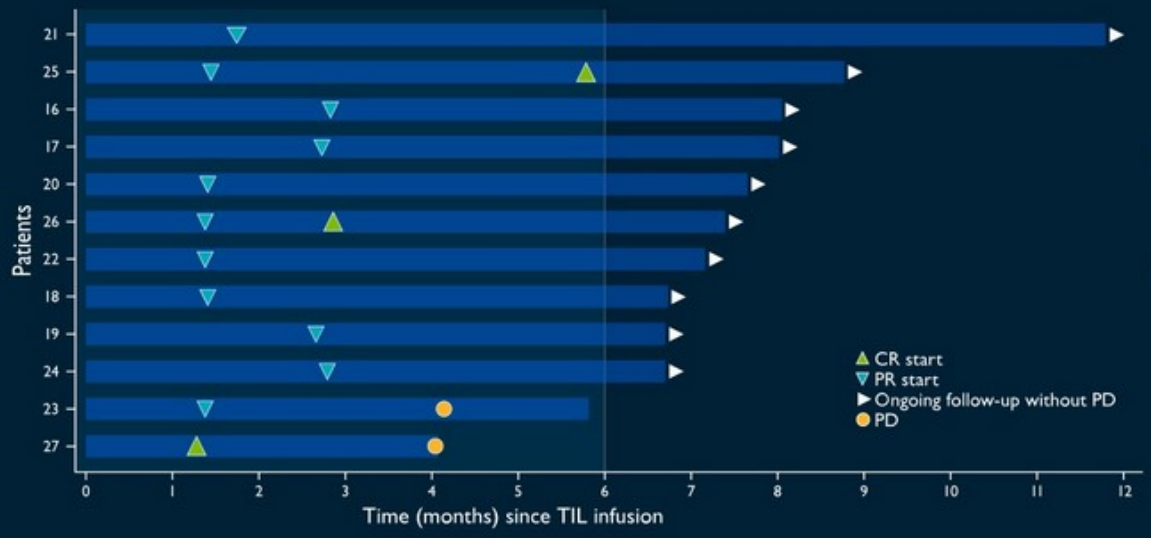
Responses Observed Early On and Consistent with Melanoma

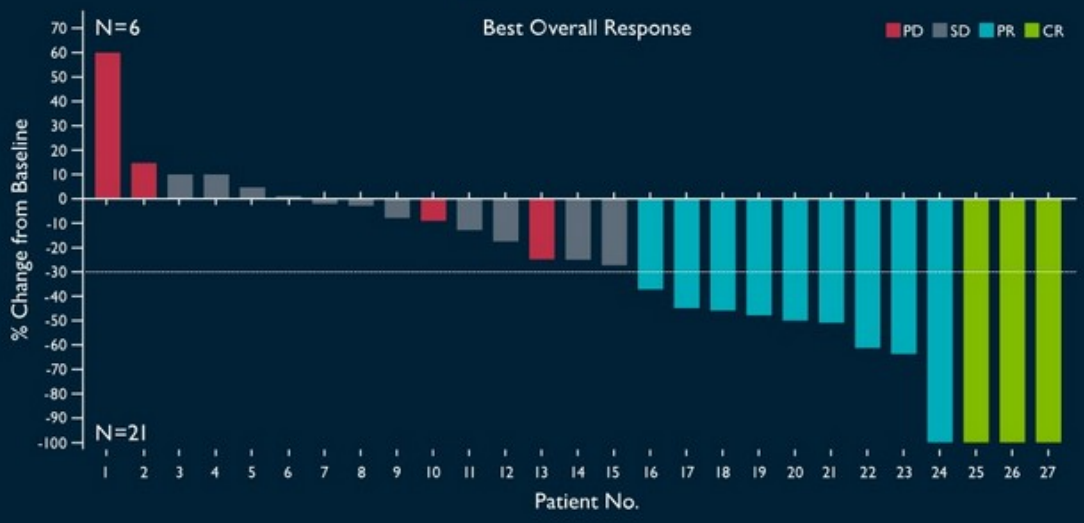
Lifileucel time to response and current duration for evaluable patients (partial response or better)



- Mean time to first response 1.9 months
- Mean time to best response 2.4 months

Three Complete Responses Observed with Lifileucel

Lifileucel best overall response rate



- 78% of patients had a reduction in tumor burden
- Mean time to response 1.9 months
- All assessments are by RECIST 1.1
- Responses are deep with majority of responders are over 30%

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Development Efforts in Recurrent, Metastatic or Persistent Cervical Carcinoma

Recurrent, metastatic, or persistent cervical carcinoma has no current standard of care

Agent	ORR % (N)	Current Dev Status	Prior Line of Tx	Patient Characteristics
Antibody-drug conjugate				
tisotumab vedotin (TV) (Genmab/Seattle Genetics)	24% (N=101)[1]	Phase 2	1+	Recurrent or metastatic cervical cancer that progressed on standard therapy (most had received at least two prior therapies), median DOR=8.3 months, median OS=12.1 months
Anti-PD-1				
AGEN2034 (Agenus)	14% (N=160)[2]	Phase 2	1+	Patients must have relapsed after a platinum-containing doublet administered for treatment of advanced disease, median DOR=15.4 months
cemiplimab (Regeneron)	10% (N=10)[3]	Phase 3	2+	Recurrent or metastatic cervical cancer resistant to, or intolerant of, platinum therapy
TKI				
neratinib (Puma Biotechnology)	27% (N=11)[4]	Phase 2	2	Metastatic HER2-positive cervical cancer (percentage of HER2+ in cervical cancer is ~3.9%)[5]
Cell therapies				
TIL (lifileucel)	**44% (N=27)**	**Phase 2**	**2.4 (mean)**	**All patients progressed on or after chemo; median DOR not reached (median follow-up 7.4 months)**

[1] Coleman, et al., ESMO 2020; [2] O'Malley, et al. ESMO 2020; [3] Rischin, et al. ESMO 2018; [4] D'Souza et al. SGO 2019; [5] Yan, et al. *Cancer Metastasis Rev.* 2015

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Additional Solid Tumor Studies

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Non-Small Cell Lung Cancer (NSCLC)

Efficacy Data Post Moffitt TIL Infusion

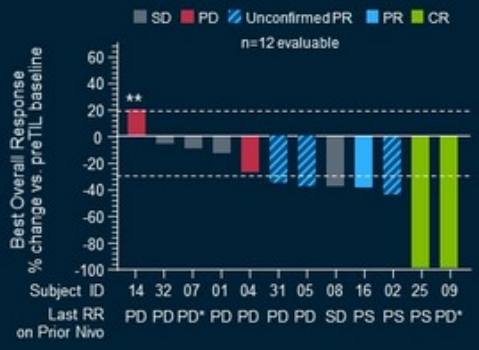
Responses	N=12 (%)
Objective Response Rate	**3 (25%)**
Complete Response	2 (17%)
Partial Response	1 (8%)

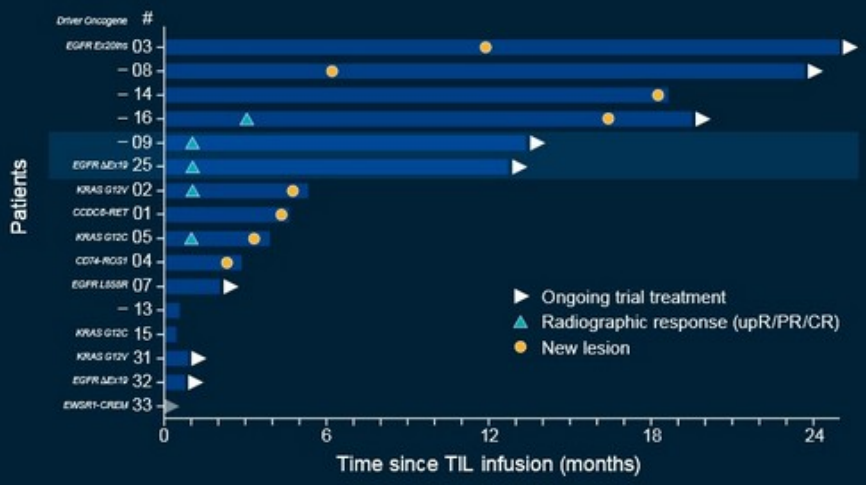
- **ORR 25%;**
  - 1 CR is noted in $EGFR^{\Delta Ex19}$ post afatinib, osimertinib, nivolumab
  - 1 additional uPR may confirm to increase the ORR to 33%
- **Median DOR not reached;**
  - All 3 responders on TIL were relapsed or refractory to monotherapy Nivo
  - The TIL CR responses were ongoing
  - 2/3 responders were PD-L1 low (TPS<5%)

Moffitt TIL in Post-Nivolumab NSCLC

Nivolumab and Tumor Infiltrating Lymphocytes (TIL) in Advanced Non-Small Cell Lung Cancer (NCT03215810)

Post-TIL





In 12 evaluable patients with advanced NSCLC who received nivolumab and TIL:

- Two CRs out to one year
  - (PD-L1 low=1, EGFR mutation=1)
- ORR 25% (or 33% if a uPR confirms)

[1] Creelan, et. al., Durable complete responses to adoptive cell transfer using tumor infiltrating lymphocytes (TIL) in non-small cell lung cancer (NSCLC): a phase I trial, AACR 2020, Abstract #20-LB-10617

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TIL in Earlier Lines of Therapy in Combination with SOC

A prospective, open-label, multi-cohort, non-randomized, multicenter Phase 2 study evaluating adoptive cell therapy (ACT) with TIL LN-144 (Lifileucel)/LN-145 in combination with pembrolizumab or TIL LN-145/LN-145-S1 as a single therapy (NCT03645928)

Endpoints

- Primary: ORR and safety
- Secondary: CR rate

Study Updates

- 28 sites are activated globally
- Sites in the U.S., Canada and Europe

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Research Focus into Next Generation TIL

Expand the TIL platform into new indications/regimens

- First patient dosed in Phase 1/2 study for PBL in CLL
- IOV-3001 IL-2 analog licensed from Novartis

Select more potent TIL

- PD-1 positive selected TIL by Iovance
- PD-1 positive selected TIL also through collaboration with CHUM

Genetically modify to make a more tumor-reactive TIL

- Cellectis TALEN® collaboration agreement in place to support a clinical program

Process optimization

- Gen 3 (16-day) process
- Core biopsy

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Iovance Biotherapeutics Global Reach and Scale

Iovance Biotherapeutics has >200 employees

- Headquartered in San Carlos, CA
- 3 additional offices
- Iovance commercial manufacturing facility in Philadelphia, PA *(under construction)*

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Well Capitalized in Pursuit of TIL Commercialization

June 30, 2020	In millions (unaudited)
Common shares outstanding	146[1]
Preferred shares	4[2]
Options	12
Cash, cash equivalents, short-term investments, restricted cash	$777.4[3]
Anticipated year-end cash balance	>$630[3]
Debt	$0

[1] Includes May 2020 offering of 19,475,806 shares of common stock
[2] Preferred shares are shown on an as-converted basis
[3] Includes Restricted Cash of $5.5 million

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Milestones 2020-2021

- [x] Last patient dosed in Cohort 4 for lifileucel in support of registration in melanoma
- [x] Data presentation at ASCO for long term follow up of melanoma Cohort 2
- [x] Early cohort 4 data from melanoma
- [ ] Last patient dosed in pivotal program of lifileucel for cervical cancer
- [ ] Hold a pre-BLA meeting with FDA
- [ ] Initiate NSCLC registration-supporting study
- [ ] Submit BLA for lifileucel

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Thank You

Exhibit 99.2

Iovance Biotherapeutics Provides Update for Lifileucel in Metastatic Melanoma

SAN CARLOS, Calif., October 5, 2020 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today provided a regulatory update for its tumor-infiltrating lymphocyte (TIL) therapy lifileucel in metastatic melanoma. In preparation for the planned Biologics License Application (BLA) submission for lifileucel, the Company has been engaged in discussions with the U.S. Food and Drug Administration (FDA), including a recent Type B meeting, regarding the requirements and timing of certain information that would be provided as part of its BLA submission.

The Company believes that clinical data from its C-144-01 trial supports the potential for lifileucel as a treatment for metastatic melanoma. Iovance and the FDA have reached agreement on the duration of follow up for its pivotal Cohort 4 to support the BLA submission. As part of the Type B meeting, the Company and the FDA have not been able to agree on the required potency assays to fully define its TIL therapy, which is required as part of a BLA submission. The Company is continuing to refine the information from its current potency assays and simultaneously developing additional assays. As a result of these developments, the BLA submission is not expected by the end of 2020. The Company will continue to work closely with the FDA and now anticipates a BLA submission to occur in 2021. Additional guidance on the BLA submission timing will be provided when available.

“TIL is a first-in-class, one-time administration cell therapy targeting solid tumors. As such, definition of the product through a potency assay is an important step toward submission of the BLA,” stated Maria Fardis, Ph.D., MBA, Iovance President and Chief Executive Officer. “We have agreement with the FDA regarding the amount of clinical follow up for the BLA, and we will work closely with the FDA to reach alignment on our assays. Because Iovance recognizes the significant unmet need in the melanoma patient population and believes the compelling clinical data for lifileucel will offer a new therapy for such patients, we are moving ahead with a great sense of urgency. We look forward to further collaboration with the FDA and will provide updates as they become available.”

As previously announced, updated Cohort 2 data from the C-144-01 clinical trial presented at the 2020 American Society of Clinical Oncology Annual Meeting showed an overall response rate (ORR) of 36.4 percent with a median duration of response not reached at 18.7 months of median study follow up (n=66). Early Cohort 4 data previously reported by the Company showed an ORR of 32.4 percent at 5.3 months of median study follow up (n=68). Currently available treatment options for the patient population in the C-144-01 study is limited to chemotherapy, with a response rate of four to 10 percent and a very short duration of response.

Webcast and Conference Call
The Company will host a conference call today at 4:30 p.m. ET. The conference call dial-in numbers are 1-844-646-4465 (domestic) or 1-615-247-0257 (international). The conference ID access number for the call is 5866866. The live webcast can be accessed in the Investors section of the Company’s website at http://www.iovance.com. The archived webcast will be available for a year in the Investors section at www.iovance.com.

About Iovance Biotherapeutics, Inc.
Iovance Biotherapeutics aims to improve patient care by making T cell-based immunotherapies broadly accessible for the treatment of patients with solid tumors and blood cancers. Tumor infiltrating lymphocyte (TIL) therapy uses a patient’s own immune cells to attack cancer. TIL cells are extracted from a patient’s own tumor tissue, expanded through a proprietary process, and infused back into the patient. After infusion, TIL reach tumor tissue, where they attack tumor cells. The Company has completed dosing in the pivotal study in patients with metastatic melanoma and is currently conducting a pivotal study in patients with metastatic cervical cancer. In addition, the Company’s TIL therapy is being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including head and neck and non-small cell lung cancer. A clinical study to investigate Iovance T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) therapy is open to enrollment. For more information, please visit www.iovance.com.

Forward-Looking Statements

Certain matters discussed in this press release are "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "us," or "our") within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). All such written or oral statements made in this press release, filings with the Securities and Exchange Commission ("SEC"), reports to stockholders and in meetings with investors and analysts, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by the PSLRA. Without limiting the foregoing, we may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "forecast," "guidance," "outlook," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the success, timing, projected enrollment, manufacturing and production capabilities, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates (including both Company-sponsored and collaborator-sponsored trials in both the U.S. and Europe), such as statements regarding the timing of initiation and completion of these trials; the strength of the Company's product pipeline; and the guidance provided for the Company's future cash, cash equivalents, short term investment, restricted cash balances, and forecasted operating expenses. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements, including, without limitation, the following substantial known and unknown risks and uncertainties inherent in the Company's business: the COVID-19 pandemic may have an adverse effect on the Company and its clinical trials, including potential slower patient recruitment, inability of clinical trial sites to collect data, inability of the Company or its contract research organizations to monitor patients, as well as U.S. Food and Drug Administration ("FDA") availability due to competing priorities; our ability to achieve long-term profitability and successfully commercialize our products alone or with third parties, as well as our history of operating losses and our expectations that we will continue to incur significant operating losses; our limited operating history in our current line of business, which makes it difficult to evaluate our prospects, our business plan or the likelihood of our successfully implementing such business plan; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates (including, with respect to lifileucel for the treatment of metastatic melanoma, reaching agreement with the FDA on the appropriate potency assay and the timing to submit a biologics licensing application ("BLA") to the FDA), and our ability to successfully commercialize any product candidates for which we obtain FDA approval; our limited history in conducting clinical trials, on which our future profitability is substantially dependent, and our need to rely on third parties, including contract research organizations, contract manufacturing organizations and consultants, in connection with the conduct, supervision and monitoring of our clinical trials for our product candidates; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; the risk that a slower rate of enrollment may delay the Company's clinical trial timelines or otherwise adversely impact our clinical development activities; the risk that enrollment may need to be adjusted for the Company's trials and cohorts within those trials based on FDA and other regulatory agency input; the new version of the protocol which further defines the patient population to include more advanced patients in the Company's cervical cancer trial may have an adverse effect on the results reported to date; the risk that the results obtained in our ongoing clinical trials may not be indicative of results obtained in future clinical trials or that data within these trials may not be supportive of product approval, including that later developments with the FDA may be inconsistent with already completed FDA meetings; the risk that the FDA may not agree with our approach to expand our cervical cancer trial to include Cohort 2 of the C-145-04 trial; the risk that changes in patient populations may result in changes in preliminary clinical results; the Company's ability or inability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical, safety, manufacturing and control requirements; the risk that regulatory authorities may potentially delay the timing of FDA or other regulatory approval of, or other action with respect to, our product candidates, or that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA or other regulatory authorities; the risk that the Company's interpretation of the results of its clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; our ability to obtain and maintain intellectual property rights related to our product pipeline; our ability to successfully implement our research and development programs and collaborations; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability to obtain tax incentives and credits and the risk that our existing net operating loss carryforwards and research tax credits may expire or otherwise be limited in use; the success of our manufacturing, license or development agreements; risks related to the Company's ability to maintain and benefit from accelerated FDA review designations, including breakthrough therapy designation or regenerative medicine advanced therapy designation, which may not result in a faster development process or review of the Company's product candidates (and which may later be rescinded by the FDA), and which does not assure approval of such product candidates by the FDA or the ability of the Company to obtain FDA approval in time to benefit from commercial opportunities; the ability or inability of the Company to manufacture its therapies using third party manufacturers or its own facility may adversely affect the Company's potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in the Company's sponsored trials; our dependence on additional financing to fund our operations and complete the development and commercialization of our product candidates, and the risks that raising such additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidates; the risk that additional expenses may decrease our estimated cash balances and increase our estimated capital requirements; and other factors that may have a material adverse effect on the Company's business and clinical development, including general economic conditions, the Covid-19 pandemic and regulatory developments, not within the Company's control.

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