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): November 9, 2018

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. ☐

Item 8.01. Other Events.

Iovance Biotherapeutics, Inc. (the "Company") from time to time makes presentations at healthcare conferences and to analysts, current stockholders, and others. A copy of the Company's presentation that it intends to use during November 2018 is filed as Exhibit 99.1 to this current report on Form 8-K and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Iovance Biotherapeutics, Inc., Presentation - November 2018.

SIGNATURES

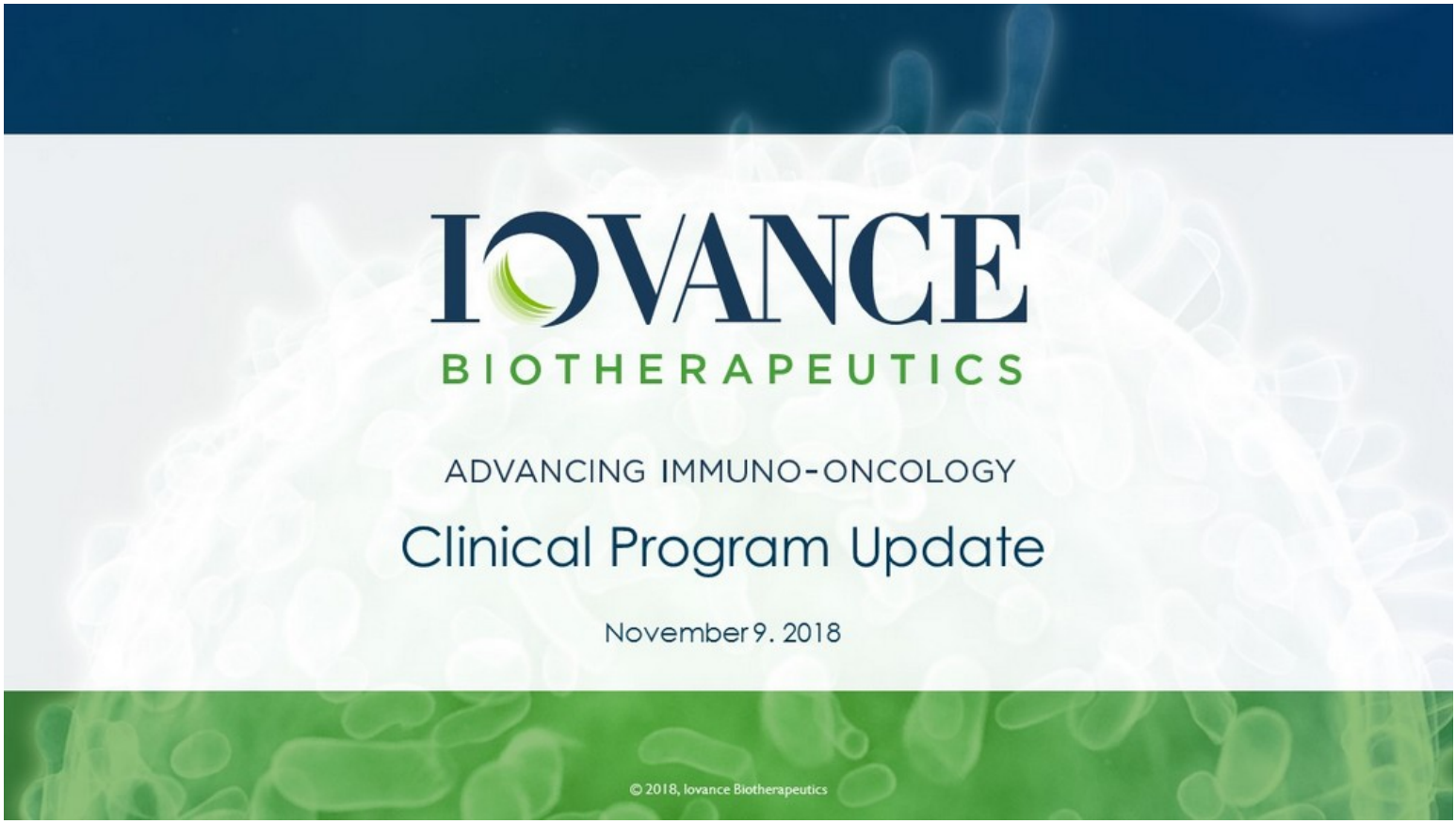
Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 9, 2018

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1


IOVANCE
BIOTHERAPEUTICS
ADVANCING IMMUNO-ONCOLOGY
Clinical Program Update
November 9. 2018
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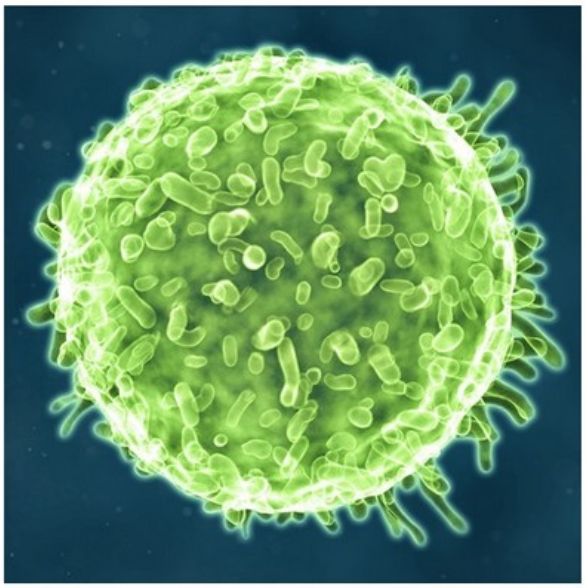
Forward-Looking Statements

This presentation contains "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "us," or "our"). We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. The forward-looking statements include, but are not limited to, risks and uncertainties relating to the success, timing, projected enrollment, manufacturing 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 timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; the strength of Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's manufacturing, license or development agreements; the acceptance by the market of the Company's product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the FDA may not agree with the Company's interpretation of the results of its clinical trials; later developments with the FDA that may be inconsistent with already completed FDA meetings; the preliminary clinical results, including efficacy and safety results, from ongoing Phase 2 studies described above may not be reflected in the final analyses of these trials including new cohorts within these trials; the results obtained in the Company's ongoing clinical trials, such as the studies and trials referred to in this release, may not be indicative of results obtained in future clinical trials or supportive of product approval; regulatory authorities may potentially delay the timing of FDA or other regulatory authority approval of, or other action with respect to, the Company's product candidates (specifically, the Company's description of FDA interactions are subject to FDA's interpretation, as well as FDA's authority to request new or additional information); the Company may not be able to obtain or maintain FDA or other regulatory authority approval of its product candidates; the Company's ability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical and safety requirements as well as manufacturing and control requirements; risks related to the Company's accelerated FDA review designations; the ability of the Company to obtain and maintain intellectual property rights relating to its product pipeline; and the acceptance by the market of the Company's product candidates and their potential reimbursement by payors, if approved.

For more detailed information about the risks and uncertainties that could cause actual results to differ materially from those implied by, or anticipated in, these forward-looking statements, please refer to the Risk Factors section of the Company's Annual Report on Form 10-K and subsequent updates that may be contained in the Company's Quarterly Reports on Form 10-Q and current reports on Form 8-K on file with the SEC. Forward-looking statements speak only as to the date they are made. Except as required by law, the Company does not undertake to update forward-looking statements to reflect circumstances or events that occur after the date the forward looking statements are made. This presentation does not constitute an offer to sell or buy securities, and no offer or sale will be made in any state or jurisdiction in which such offer or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

TIL Therapy Elicits a Highly Individualized, Specific and Potent Attack Against Solid Tumors

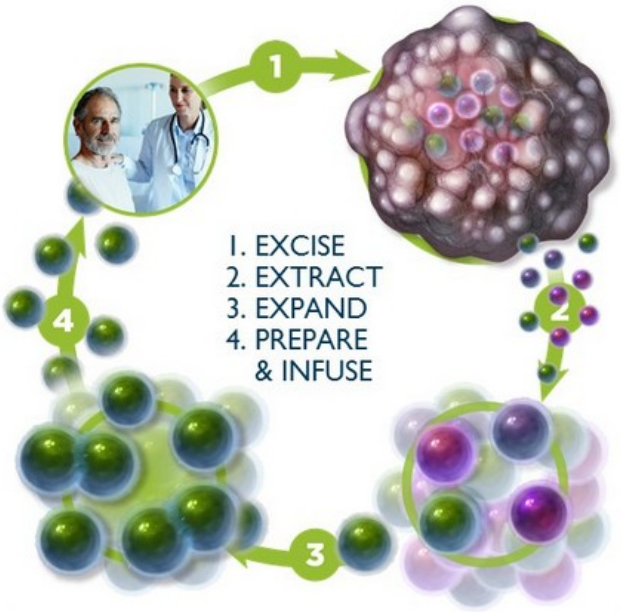
- Leverages and enhances the body's natural defense against cancer using a patient's own TIL
- Polyclonal and can recognize multiple neoantigens
  - Solid tumors are heterogeneous
- Durable response with single treatment
- Potential to establish immunological memory, requiring no additional maintenance therapy after infusion
  - Responses seen both in treatment naïve and refractory melanoma patients who have failed other options, including checkpoint inhibitors
  - Complete responses observed at **53** and **67** months in cervical cancer patients[1]



[1] Stevanovic, et al., Treatment of Metastatic Human Papiliomavirus-Associated Epithelial Cancers with Adoptive Transfer of Tumor-Infiltrating T Cells, ASCO 2018, Abstract #3004

IOVANCE BIOTHERAPEUTICS

TIL Therapy Process



- EXCISION: Patient's TIL are removed from suppressive tumor microenvironment (via surgical resection of a lesion)
- EXTRACTION: Tumor is fragmented and placed in media for TIL to leave the tumor and enter media
- EXPANSION: TIL expanded exponentially *ex vivo* to yield $10^9 – 10^{11}$ TIL
- PREPARATION: Patient receives non-myeloablative lymphodepletion to eliminate potentially suppressive tumor microenvironment and maximize engraftment and potency of TIL therapy:
  - cyclophosphamide: 60 mg/kg x 2 doses
  - fludarabine: 25 mg/m^2 x 5 doses
- INFUSION: Patient is infused with their expanded TIL and IL-2 (600,000 IU/kg, up to 6 doses) to promote activation, proliferation and anti-tumor cytolytic activity of TIL

IOVANCE BIOTHERAPEUTICS

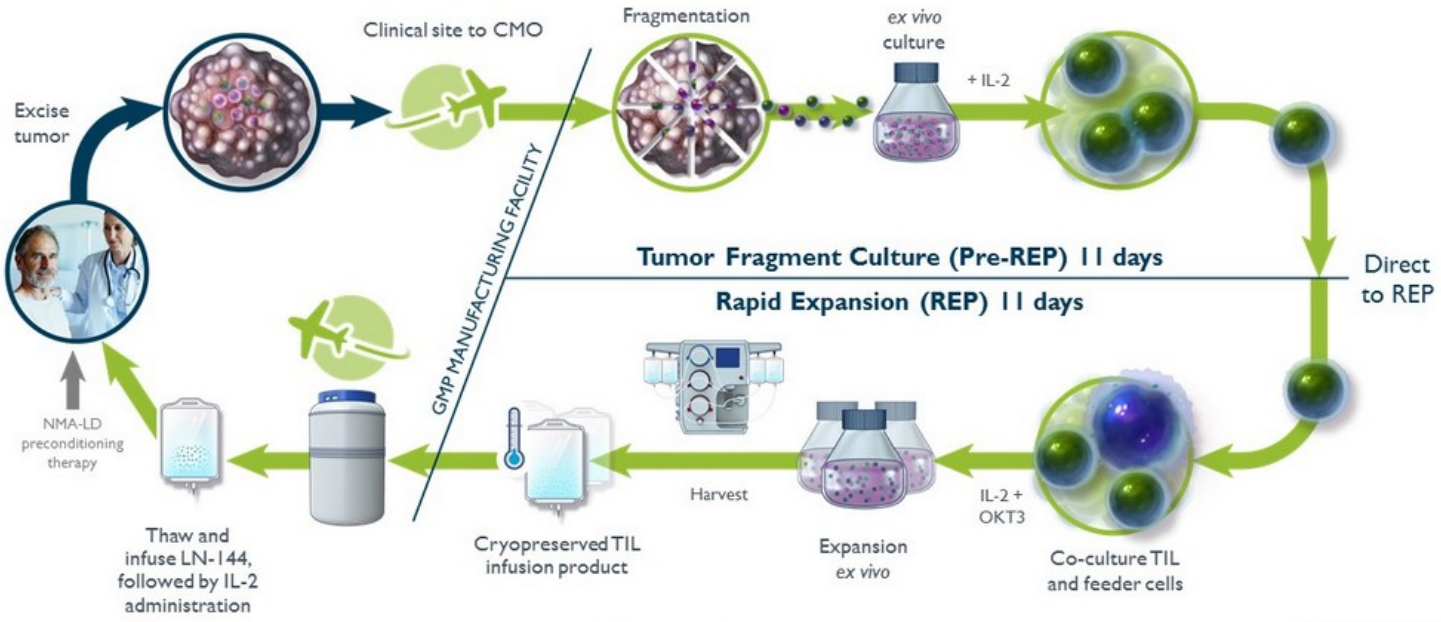
Iovance Accomplishments since 2016

- ☑ Developed a proprietary centralized and commercial CMC process ("Gen 2")
- ☑ Replicated / demonstrated clinical activity using our novel Gen 2 process in melanoma post-checkpoint inhibitors (CPI)
- ☑ Identified a fast-to-market registration pathway with FDA
- ☑ Demonstrated activity in other tumor types post-CPI
- ☑ Generated new Iovance IP around TIL technology and CMC

TIL – Tumor Infiltrating Lymphocyte; Checkpoint inhibitors (CPI) include anti-PD1, anti-PD-L1 and anti-CTLA4 therapy

IOVANCE BIOTHERAPEUTICS

Cryopreserved Autologous TIL (lifileucel, LN-144) Manufacturing Process: 22-days



Iovance Corporate Overview

- Developing and commercializing tumor infiltrating lymphocyte (TIL) therapies as a **platform for treatment of cancers**
- **Robust Clinical Development Pipeline:**
  - Iovance pipeline of 5 company-sponsored Phase 2 trials
    - **Metastatic melanoma** C-144-01
      - **Orphan Drug Designation**
      - **Fast Track**
      - **RMAT**
      - **Starting the registration-enabling cohort**
    - **Cervical** C-145-04
      - **Orphan Drug Designation**
    - **Head and neck** C-145-03
    - **NSCLC** IOV-LUN-201
    - **Basket study** IOV-COM-202

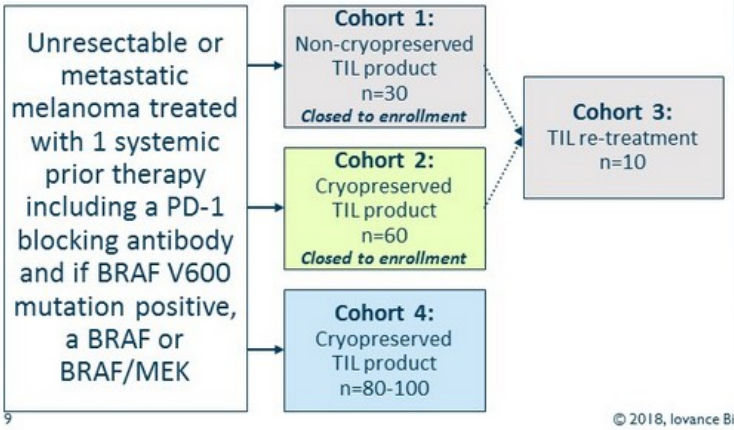
- **Manufacturing Fully in Place:**
  - TIL clinical and commercial manufacturing capabilities in U.S. and E.U.
  - 22 day manufacturing process
  - Greater than 90% manufacturing success
  - US Patents Allowed
- **Large Team of Collaborators for TIL Development:**
  - MD Anderson Cancer Center
  - Moffitt Cancer Center
  - MedImmune/AstraZeneca
  - National Cancer Institute/NIH
  - Ohio State University
  - Roswell Park Cancer Institute

IOVANCE BIOTHERAPEUTICS

Iovance C-144-01 SITC Data Presentation

Iovance C-144-01 Study Design

Phase 2, multicenter study to assess the efficacy and safety of autologous Tumor Infiltrating Lymphocytes (LN-144) for treatment of patients with metastatic melanoma (NCT02360579)



Endpoints:

- Primary: Efficacy defined as investigator ORR
- Secondary: Safety and efficacy

Study Updates:

- Cohort 2 fully enrolled & closed to new enrollment
- Cohort 2 Preliminary efficacy and safety data presented here (n=47, Data extract as of 25 Oct 2018)

Cohort 4 will initiate in early 2019 (registration-enabling):

- 80-100 patients
- BIRC ORR endpoint

COHORT 2

Iovance C-144-01 Patient Characteristics:

CHARACTERISTIC	Cohort 2, N=47, (%)
Gender, n (%)	
Male	27 (57)
Female	20 (43)
Age	
Median	56
Min, Max	30, 77
Prior therapies, n (%)	
Mean # prior therapies	3.3
Anti-CTLA-4	37 (79)
Anti-PD-1	47 (100)
BRAF/MEK	12 (26)
Target Lesions Sum of Diameter (mm)	
Mean (SD)	112 (73)
Min, Max	17, 343

CHARACTERISTIC	Cohort 2, N=47, (%)
Baseline ECOG score, n (%)	
0	27 (57)
1	20 (43)
BRAF Status, n (%)	
Mutated V600	14 (30)
Wild Type	32 (68)
Unknown	1 (2)
Baseline LDH (U/L)	
Median	246
1-2 times ULN	12 (26)
> 2 times ULN	7 (15)
Number of Target & Non-Target Lesions (at Base Line)	
>3	37 (79)
Mean	6

Cohort 2 has:

- 3.3 mean prior therapies, ranging from 1-9
- High tumor burden at baseline: 112 mm mean sum of diameters for the target lesions

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COHORT 2

Iovance C-144-01 Safety:
Treatment Emergent Adverse Events (≥ 30%)

PREFERRED TERM	Cohort 2 (N=47)		
	Any Grade, n (%)	Grade 3/4, n (%)	Grade 5, n (%)
Number of patients reporting at least one Treatment-Emergent AE	47(100)	45 (95.7)	2 (4.3)
Thrombocytopenia	42 (89.4)	38 (80.9)	0
Chills	36 (76.6)	3 (6.4)	0
Neutropenia	29 (61.7)	25 (53.2)	0
Febrile neutropenia	28 (59.6)	25 (53.2)	0
Anemia	27 (57.4)	22 (46.8)	0
Pyrexia	25 (53.2)	7 (14.9)	0
Hypophosphatemia	23 (48.9)	17 (36.2)	0
Leukopenia	21 (44.7)	20 (42.6)	0
Fatigue	17 (36.2)	0	0
Hypotension	17 (36.2)	4 (8.5)	0
Lymphopenia	17 (36.2)	17 (36.2)	0
Tachycardia	15 (31.9)	1 (2.1)	0

* One death was due to intra-abdominal hemorrhage considered possibly related to TIL and one was due to acute respiratory failure not related to TIL per investigator assessment.
Patients with multiple events for a given preferred term are counted only once using the maximum grade under each preferred term.
Treatment-Emergent Adverse Events refer to all AEs starting on or after the first dose date of TIL up to 30 days.
Safety terms which describe the same medical condition, were combined

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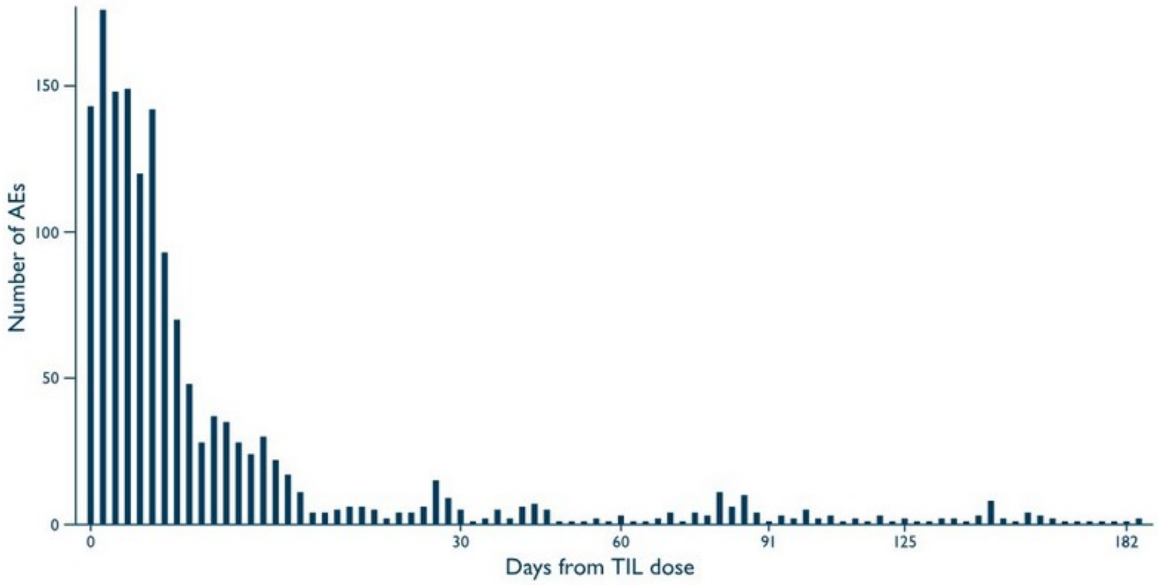
COHORT 2

Iovance C-144-01 Safety:

Adverse Events over Time

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



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COHORT 2

Iovance C-144-01 Efficacy

- Median DOR is 6.4 months
- Range of DOR was from 1.3+ to 14+ months

RESPONSE	PATIENTS, N=47 n (%)
Objective Response Rate	**18 (38%)**
Complete Response	1 (2%)
Partial Response (PR+ uPR[1])	17 (36%)
Stable Disease	18 (38%)
Progressive Disease	7 (15%)
Non-Evaluable*	4 (9%)
Disease Control Rate	36 (77%)

* NE due to not reaching first assessment
[1] uPRs (4) were not confirmed yet due to not having reached the second assessment as of 25 Oct 2018

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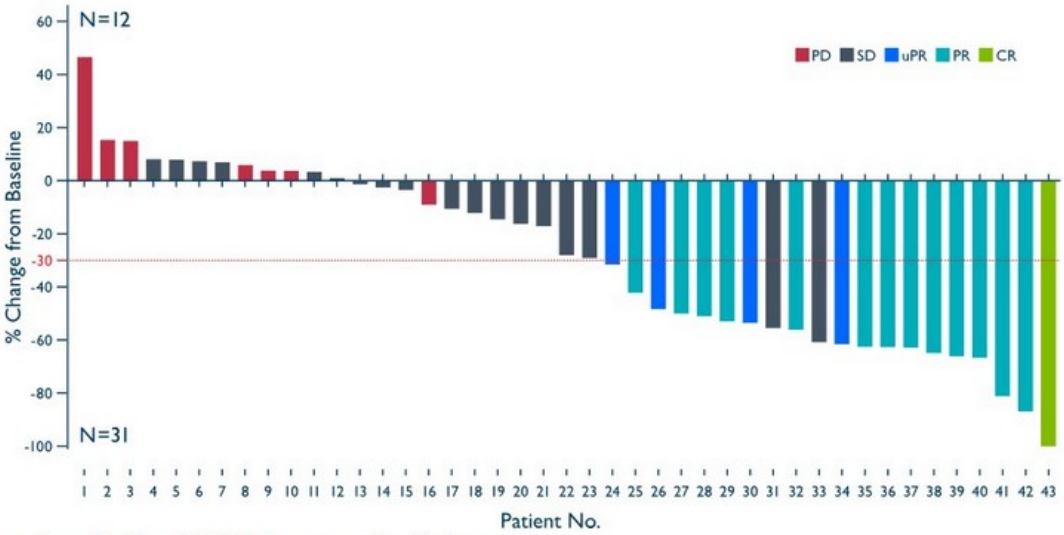
COHORT 2

Iovance C-144-01 Efficacy

Best Overall Response

- Mean number of TIL cells infused: 26 x 10^9
- Median number of IL-2 doses administered was 6.0
- 72% of patients had a reduction in tumor burden
- Median study follow up is 6.0 months



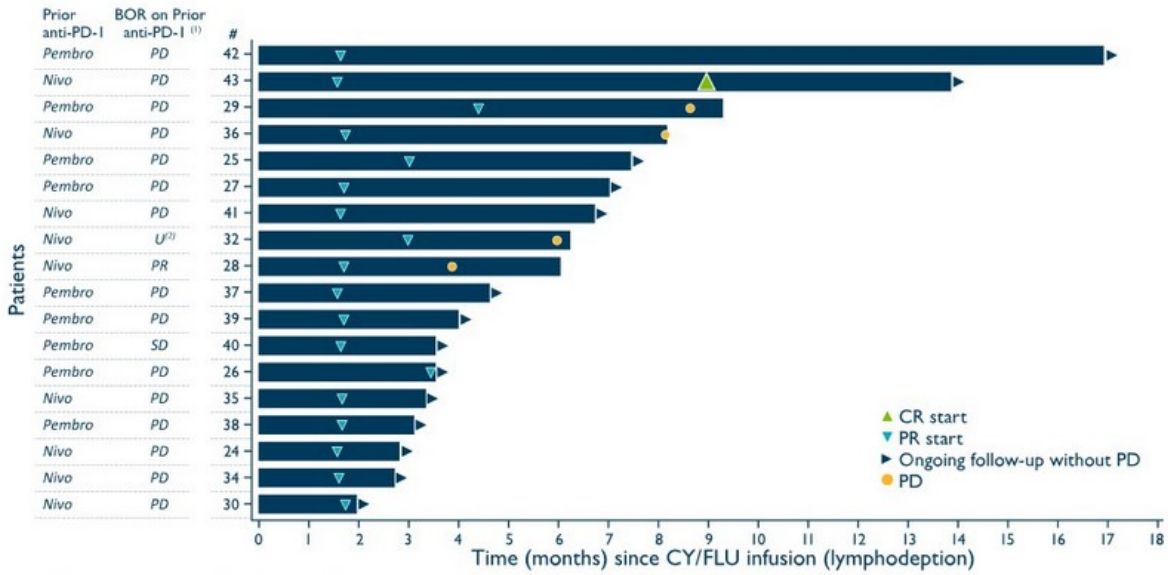
Four patients who had no disease assessment following autologous TIL (lifileucel, LN-144) due to cancer-related death are not shown
Per RECIST 1.1, two patients (31,33) had BOR of SD: met PR criteria at Day 42 and PD at Day 84 due to new lesions

IOVANCE BIOTHERAPEUTICS

COHORT 2

Iovance C-144-01 Efficacy:

Time to Response for Evaluable Patients (PR or Better)



(1) BOR is best overall response on prior anti-PD-1 immunotherapy
(2) U: unknown best overall response on prior anti-PD-1 immunotherapy

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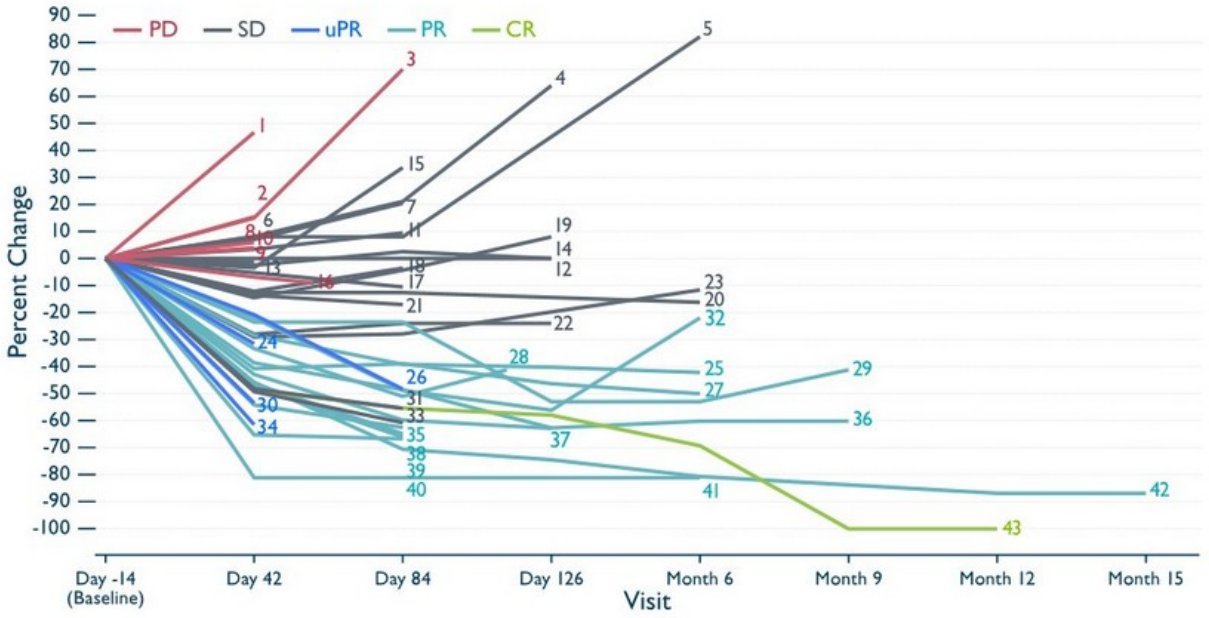
COHORT 2

Iovance C-144-01 Efficacy:

Percent Change from Baseline in Sum of Target Lesion Diameters over Time



IOVANCE BIOTHERAPEUTICS

COHORT 2

Iovance C-144-01:
Conclusions

- In heavily pretreated metastatic melanoma patients, preliminary efficacy is notable for:
  - ORR: 38%
  - Median DOR: 6.4 months, range 1.3+ to 14+
  - DCR: 77%
- 16/17 had no response to prior anti-PD-1

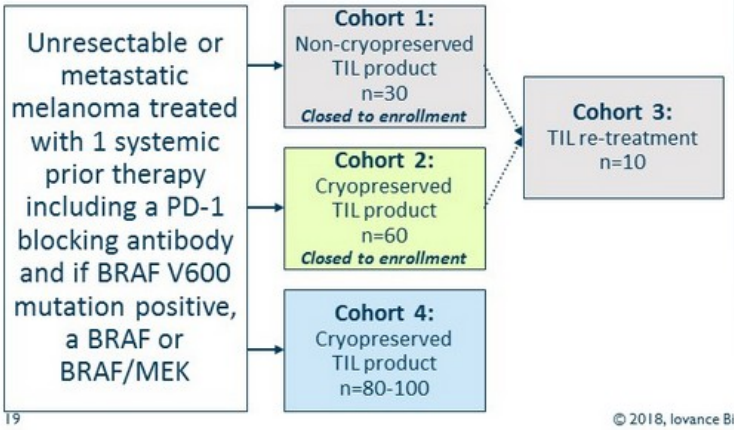
Preliminary data supports lifileucel autologous TIL as an efficacious and well-tolerated therapeutic option for patients with metastatic melanoma

IOVANCE BIOTHERAPEUTICS

Lifileucel Registration Path

Iovance C-144-01 Study Design

Phase 2, multicenter study to assess the efficacy and safety of autologous Tumor Infiltrating Lymphocytes (LN-144) for treatment of patients with metastatic melanoma (NCT02360579)



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Study Updates:

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- Cohort 2 Preliminary efficacy and safety data presented here (n=47, Data extract as of 25 Oct 2018)

Cohort 4 will initiate in early 2019 (registration-enabling):

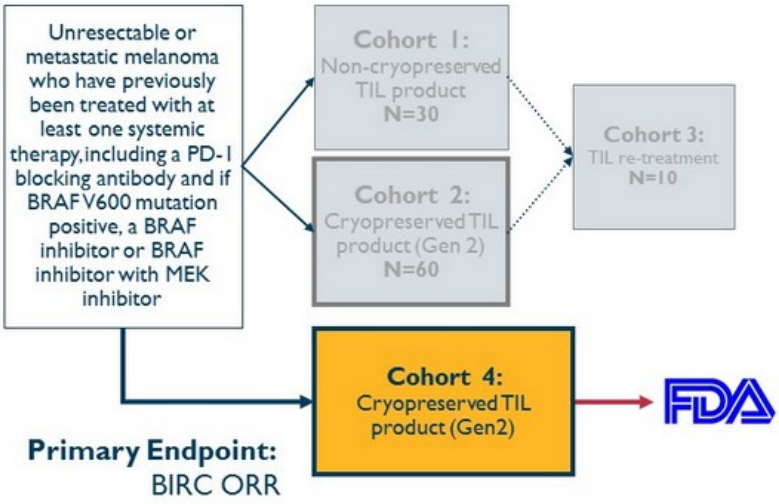
- 80-100 patients
- BIRC ORR endpoint

End-of-Phase 2 FDA Meeting has Confirmed Accelerated Single-Arm Path to Approval in Advanced Melanoma

FDA End-of-Phase 2 Meeting (Sept-18)

- FDA acknowledged acceptability of single-arm data for registration
  - Confirmed that a randomized Phase 3 study is not feasible in advanced melanoma post-CPI
- FDA recommended amending C-144-01 to add a registration-enabling cohort

Phase 2 (C-144-01): *Proposed amendment per FDA guidance*



Primary Endpoint: BIRC ORR

BICR = Blinded Independent Central Review

IOVANCE BIOTHERAPEUTICS

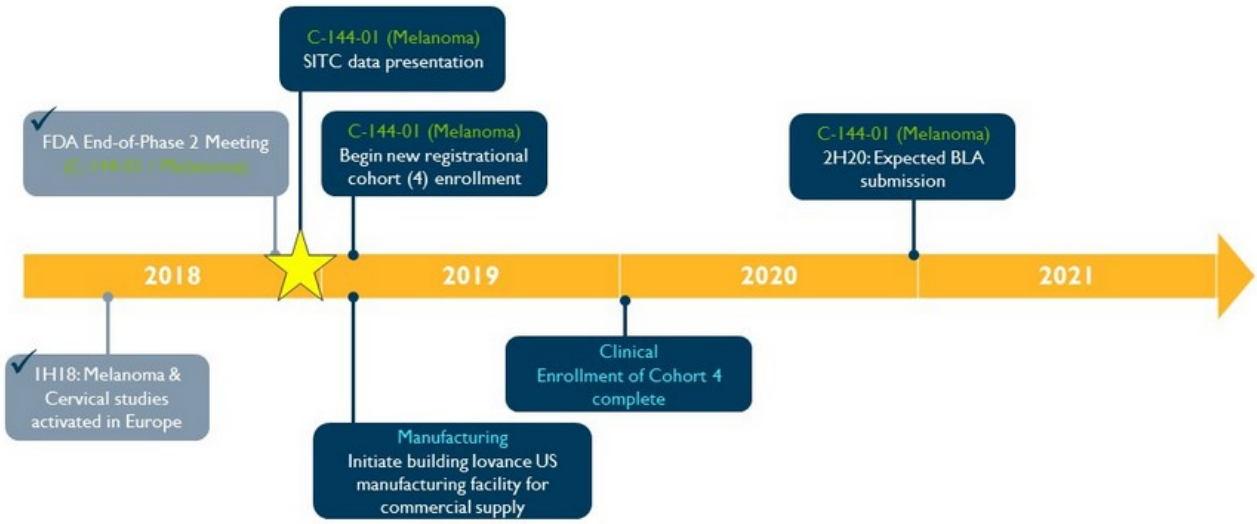
Regenerative Medicine Advanced Therapy (RMAT) Designation Received for Lifileucel for Advanced Melanoma

FDA's RMAT Designation

- Permits surrogate endpoints can be used for approval
- Provides potential for accelerated approval
- Increases sponsor access to FDA during development
- May permit a rolling review of the BLA for CBER

Fast-track and Orphan Drug Designation already awarded for advanced melanoma

Key Upcoming Melanoma and Manufacturing Milestones



LN-145 Program Update

Cervical Cancer (C-145-04)
Baseline Demographics

BASELINE DEMOGRAPHICS	PATIENTS, N=15[1] n (%)
Prior therapies, n (%)	
Median prior therapies (min, max)	5 (1, 8)
Anti-PD-1	8 (53)
Anti-CTLA-4	2 (13)

Head & Neck Cancer (C-145-03)
Baseline Demographics

BASELINE DEMOGRAPHICS	PATIENTS, N=13 n (%)
Prior therapies, n (%)	
Median prior therapies (min, max)	3 (1, 5)
Anti-PD-1	11 (85)
Anti-CTLA-4	3 (23)
Number of Target & Non-Target Lesions (at Base Line)	
>3	10 (77)

[1] The patients reported are a combination of Gen 1 and Gen 2 manufacturing processes

Cervical Cancer (C-145-04)
Safety

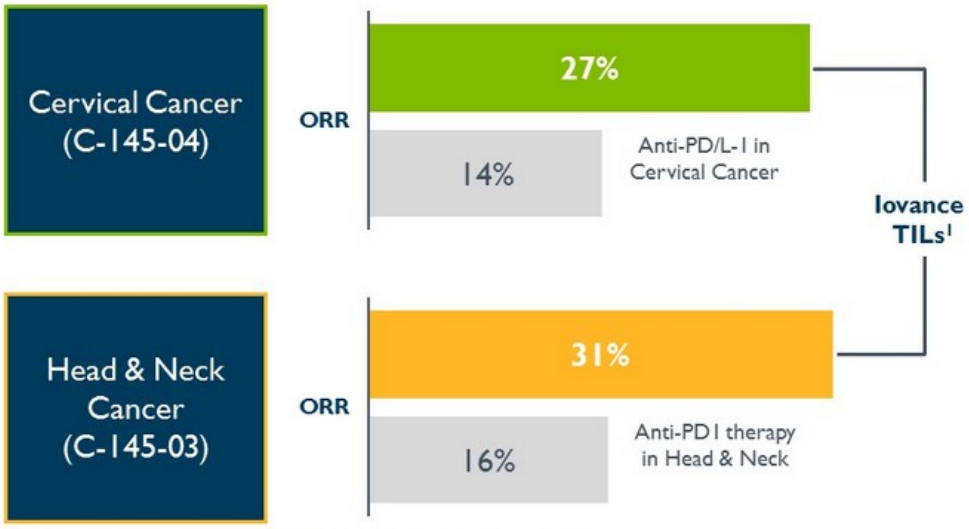
SAFETY: TEAE (≥40%) BY PT, any grade	PATIENTS, N=15 n (%)
Chills	11 (73)
Pyrexia	8 (53)
Anaemia	7 (47)
Hypotension	6 (40)
Platelet count decreased	6 (40)
Vomiting	6 (40)

Head & Neck Cancer (C-145-03)
Safety

SAFETY: TEAE (≥40%) BY PT, any grade	PATIENTS, N=13 n (%)
Chills	10 (77)
Hypotension	8 (62)
Hyponatremia	7 (54)
Pyrexia	7 (54)

TEAE: Treatment emergent adverse event
PT: Preferred term

Clinical Evidence of Efficacy in Cervical and Head & Neck Cancer post-CPI



Cervical Cancer

- N=15
- **27% ORR**
  - 4 PRs (2 to be confirmed)[2]
- **DOR** (min, max): 2.4, 2.5+ months

Head & Neck Cancer

- N=13
- **31% ORR**
  - 4 PRs
- **DOR** (min, max): 2.8, 7.6 months

[1]The patients reported are a combination of Gen 1 and Gen 2 manufacturing process
[2]uPRs were not confirmed yet due to not having reached the second assessment as of 4 Oct 2018
Note: the composition of the relevant patient population may differ between Iovance trials and published data for CPIs (USPI used) but serves as a point of reference for assessing the overall efficacy landscape for relevant therapies

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Iovance Current and Future Clinical Pipeline

INDICATION	REGIMEN	N	PARTNER	PRECLINICAL	PHASE 1	PHASE 2
Melanoma	lifileucel	85	—			C2 Enrollment closed[1] → Cohort 4[1]
Cervical Cancer	TIL LN-145	47	—			Enrolling
Head & Neck Cancer	TIL LN-145	47	—			Enrolling
Non-Small Cell Lung Cancer	TIL LN-145 + durvalumab	12	MedImmune			Open to Enrollment
Melanoma, Head & Neck, Non-Small Cell Lung Cancer	TIL LN-144 + pembrolizumab TIL LN-145 + pembrolizumab TIL LN-145	36	—			Open to Enrollment

[1] Cohort 4 enrollment is expected to start in 2019

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Iovance Collaboration Pipeline

INDICATION	REGIMEN	N	PARTNER	PRECLINICAL	PHASE 1	PHASE 2
Melanoma	Combination TIL ± TBI	101	NIH National Cancer Institute			Trial completed, 54% ORR, 24% CR
Melanoma	Combination TIL + ipilimumab	13	Moffitt Cancer Center			Trial completed
Melanoma	Combination TIL + pembrolizumab	170	NIH National Cancer Institute			Enrolling
Melanoma	Combination TIL + nivolumab	12	Moffitt Cancer Center			
Ocular (Uveal) Melanoma	TIL	23	NIH National Cancer Institute			Trial completed, 35%ORR
Ovarian, Sarcomas, new indication	TIL LN-145	~54	MD Anderson Cancer Network			Enrolling
Ovarian, Sarcomas, pancreatic	MDA TIL	~54	MD Anderson Cancer Network			Open to Enrollment
Non-small cell lung cancer	Combination TIL + nivolumab	18	Moffitt Cancer Center		Enrolling	Oral Presentation, World Conference on Lung Cancer 2018

Chandran, S. S et al., Lancet Oncol 2017; 18: 792-802.

For the studies listed in our collaboration pipeline table, the partner listed above is the sponsor of the clinical trial. Such partner may not use our Gen 2 manufacturing process and/or the therapeutic dosing may differ from our clinical trials. As a result, such partner data may not be representative of our data.

IOVANCE BIOTHERAPEUTICS

2019 Goals

- ☐ Enrollment into Cohort 4 for C-144-01 in support of registration
- ☐ Continue the dialog with FDA for both LN-144 and LN-145 in support of registration
- ☐ Initiate building Iovance manufacturing facility
- ☐ Demonstrated activity in other tumor types and lines of therapy
- ☐ Generated new Iovance IP around TIL technology and CMC

TIL – Tumor Infiltrating Lymphocyte


IOVANCE
BIOTHERAPEUTICS
ADVANCING IMMUNO-ONCOLOGY
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