

**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): September 5, 2018

IOVANCE BIOTHERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware

(State of Incorporation)

001-36860

Commission File Number

75-3254381

(I.R.S. Employer Identification No.)

**999 Skyway Road, Suite 150
San Carlos, California**

(Address of Principal Executive Offices)

94070

(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 September 2018 is furnished 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., Corporate Presentation - September 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: September 5, 2018

IOVANCE BIOTHERAPEUTICS, INC.

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



IOVANCE
BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY

Corporate Presentation

September 2018

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Forward-Looking Statements

This presentation contains forward-looking statements reflecting management's current beliefs and expectations. These forward looking statements can be identified with words such as "expects", "plans", "projects", "potential", "suggests", "may", or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Forward-looking statements in this presentation include statements regarding (i) the success and timing of our product development activities and clinical trials, (ii) our ability, and the ability of our commercial partners, to manufacture, process and deliver our product candidates and to further improve on the manufacturing process, (iii) the size of the potential markets for our product candidates, (iv) our ability to develop next generation TIL and other more effective and efficient therapeutics, (v) our ability to maintain our collaborations and other relationships with third parties, (vi) our ability to attract and retain key management and scientific personnel, (vii) our ability to obtain and maintain intellectual property protection for our product candidates, (viii) our ability to compete with other therapeutics that target the same indications as our product candidates, and (ix) our ability to achieve our manufacturing, clinical, regulatory, and other key milestones, including the progression of third-party sponsored studies, which may require additional clinical trials and manufacturing development.

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.

Iovance Corporate Highlights

- 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:** malignant melanoma stages IIB-IV
 - **Fast Track:** advanced melanoma
- **Head and neck** C-145-03
- **Cervical** C-145-04
 - **Orphan Drug Designation:** tumor size >2 cm in diameter
- **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

- **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

History of TIL: From NCI to Iovance

Indication: Solid Tumors

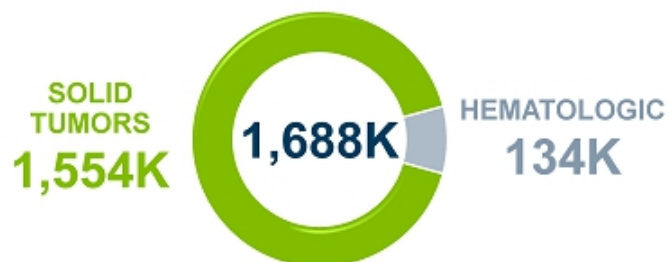
- Iovance License:
 - Rights to method of growth of TIL, selection of certain TIL, indications which include HPV associated, breast, lung, and bladder cancers and metastatic melanoma
- Strong collaboration with Dr. Steven Rosenberg at the National Cancer Institute (NCI) with rights to data and collaboration expansion opportunities

Leveraging and enhancing the utility of TIL therapy as demonstrated by Dr. Rosenberg for metastatic melanoma:

56% ORR⁽¹⁾

24% CR rate in 101 metastatic melanoma patients, durable CRs⁽²⁾

ESTIMATED NEW CASES 2017⁽³⁾



⁽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.

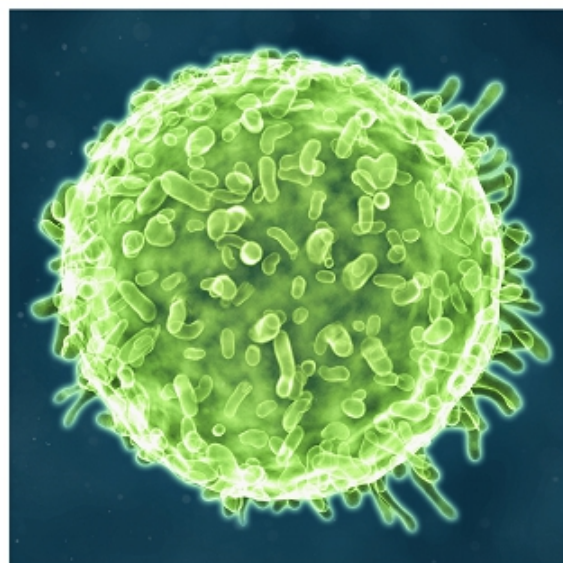
⁽³⁾ <https://seer.cancer.gov/statfacts/html/all.html>

Data from third parties may not be representative of Iovance's data.

TIL Therapy Overview

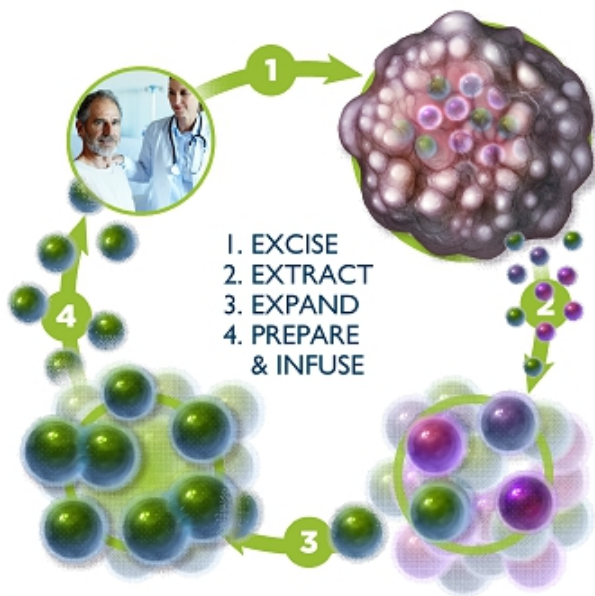
TIL Therapy Elicits a Highly Individualized, Specific and Potent Attack Against Solid Tumors

- 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 patients¹



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

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/m² 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

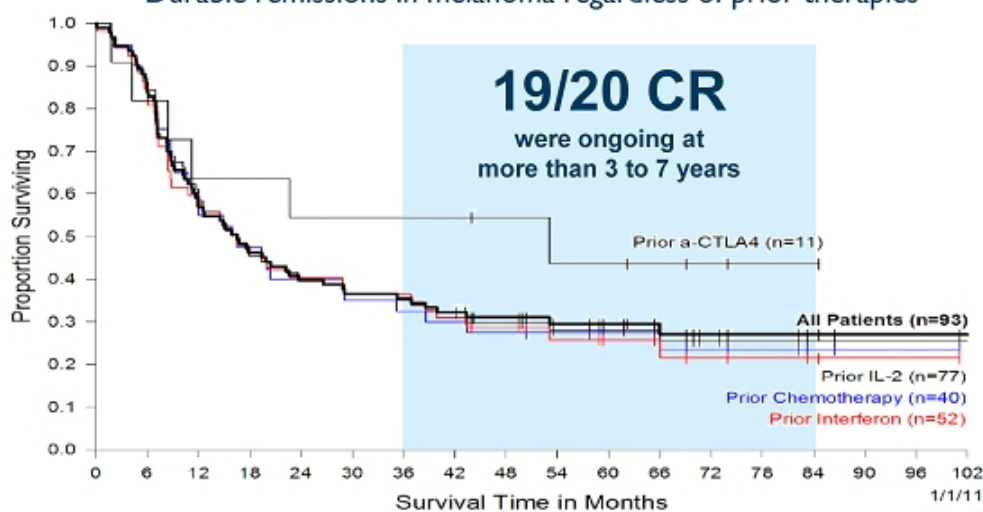
Competitive Advantages of TIL in Solid Tumors

CHECKPOINTS	TCR	CAR-T (LIQUID TUMORS)	TIL (SOLID TUMORS)
Utility in several solid tumors	Few solid tumors treated so far	No examples of successful utility in solid tumors	Available data in melanoma, head & neck, cervical and lung cancers
Long maintenance period	One-time treatment	One-time treatment	One-time treatment
No genetic modification	Genetic modification	Genetic modification	Currently, no genetic modification
Potential Long-term irreversible toxicities	Potential on-target, off-tissue effects	Potentially immunogenic: cytokine release syndrome	Minimal chance of unpredicted on-target, off-tissue effects found to date
Target multiple tumor antigens	Target only single tumor antigen	Mainly target only single/surface tumor antigen	Target multiple tumor antigens
Off-the-shelf	Autologous	Autologous	Autologous
No HLA restriction	HLA restriction	No HLA restriction	No HLA restriction

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

NCI Study Survival Benefit in Second and Third Line Patients

Durable remissions in melanoma regardless of prior therapies




IN SECOND AND THIRD LINE MELANOMA (no prior anti-PD-1)

ORR 56%




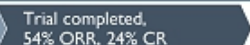

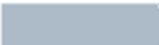

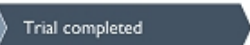



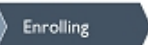

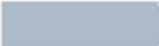




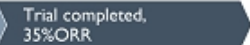
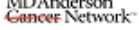


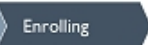



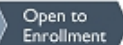

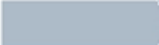


CR 22%

Rosenberg, S.A., et al. Durable Complete Responses in Heavily Pretreated Patients with Metastatic Melanoma Using T-Cell Transfer Immunotherapy. *Clinical Cancer Research*, 17(13), 4550-4557.
Data from third parties may not be representative of Iovance's data.
Abbreviations: CR, complete response; ORR, objective response rate.

Iovance Clinical Pipeline

INDICATION	REGIMEN	N	PARTNER	PRECLINICAL	PHASE I	PHASE 2
Melanoma	lifileucel	85	—			Enrolling
Cervical Cancer	TIL LN-145	47	—			Enrolling
Head & Neck Cancer	TIL LN-145	47	—			Enrolling
Non-Small Cell Lung Cancer	TIL LN-145 vs TIL LN-145 + durvalumab	24	 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

Iovance Collaboration Pipeline

INDICATION	REGIMEN	N	PARTNER	PRECLINICAL	PHASE I	PHASE 2
Melanoma	Combination TIL ± TBI	101				
Melanoma	Combination TIL + ipilimumab	13				
Melanoma	Combination TIL + pembrolizumab	170				
Melanoma	Combination TIL + nivolumab	12				
Ocular (Uveal) Melanoma	TIL	23				
Ovarian, Sarcomas, new indication	TIL LN-145	~54				
Ovarian, Sarcomas, pancreatic	MDA TIL	~54				
Non-small cell lung cancer	Combination TIL + nivolumab	18				

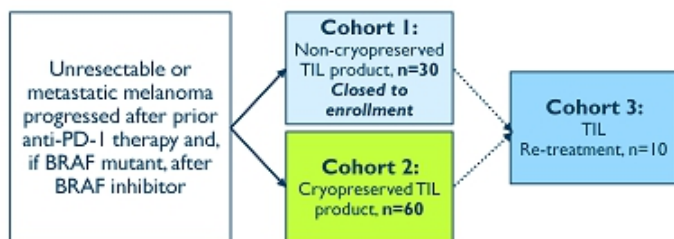
Chandran, S. S et al., Lancet Oncol 2017; 18: 792-802.

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.

Melanoma

Iovance Phase 2 Trial in Metastatic Melanoma (C-144-01)

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)



Key Inclusion Criteria:

- Measurable metastatic melanoma and ≥ 1 lesion resectable for TIL generation
- Progression on at least one prior line of systemic therapy including immune checkpoint inhibitor
- Age ≥ 18
- ECOG PS 0-1

Endpoints:

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

Study Updates:

- Cohort 2 was expanded to 60 patients
- Patient dosing commenced in EU in June 2018

Iovance C-144-01 Patient Characteristics:

Interim Data as of Dec. 2017 Data Cut

CHARACTERISTIC	Cohort 2 N=17, (%)	CHARACTERISTIC	Cohort 2 N=17, (%)
Gender, n (%)		Baseline ECOG score, n (%)	
Male	8 (47)	0	11 (65)
Female	9 (53)	1	6 (35)
Age		BRAF Status, n (%)	
Median	54	Mutated	5 (29)
Min, Max	35, 66	Wild Type	9 (53)
Prior therapies, n (%)		Unknown	3 (18)
Mean # prior systemic therapies	3.6	Baseline LDH (U/L)	
Anti-CTLA-4	15 (88)	1-2 times ULN	8 (47)
Anti-PD-1	16 (94)	> 2 times ULN	2 (12)
Target Lesion Sum of Diameter (mm)		Number of Target & Non-Target Lesions (at Base Line)	
Mean (SD)	140 (93)	>3	12 (71)
Min, Max	38, 342	Mean	5.9

* Database cut off of 1 Dec 2017

Cohort 2 has:

- 3.6 median prior therapies
- High tumor burden at baseline as reflected by 140 mm sum of diameters for target lesions

Iovance C-144-01 Safety:

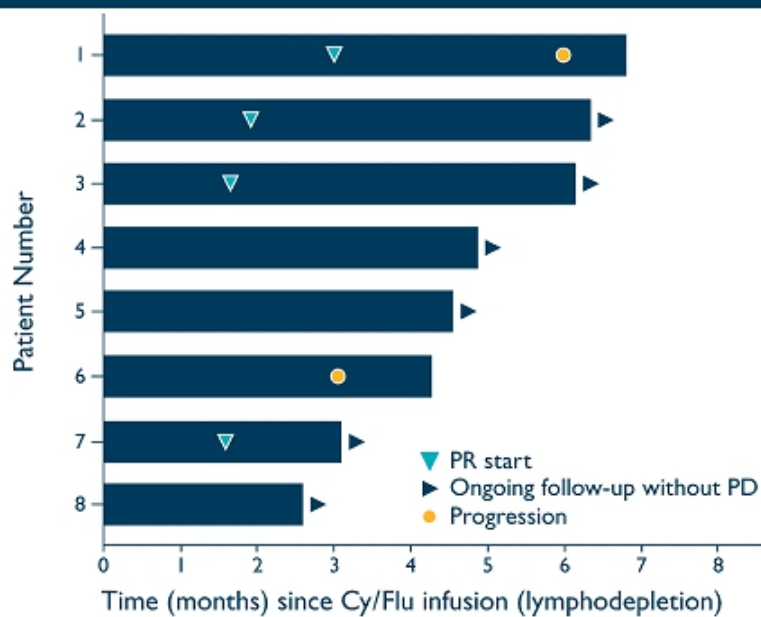
Treatment Emergent Adverse Events ($\geq 30\%$)

PREFERRED TERM	Cohort 2 (N=17)		
	Any Grade n (%)	Grade 3/4 n (%)	Grade 5 n (%)
Number of patients reporting at least one Treatment-Emergent AE	16 (94.1)	16 (94.1)	0
Pyrexia	13 (76.5)	1 (5.9)	0
Anaemia	11 (64.7)	10 (58.8)	0
Neutrophil count decreased	10 (58.8)	10 (58.8)	0
Platelet count decreased	10 (58.8)	8 (47.1)	0
Febrile neutropenia	10 (58.8)	8 (47.1)	0
Fatigue	10 (58.8)	0	0
Chills	9 (52.9)	1 (5.9)	0
Nausea	9 (52.9)	0	0
White blood cell count decreased	8 (47.1)	8 (47.1)	0
Lymphocyte count decreased	6 (35.3)	6 (35.3)	0
Diarrhoea	6 (35.3)	0	0
Decreased appetite	6 (35.3)	0	0

Notes: 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 pre-treatment chemotherapy (Fludarabine and Cyclophosphamide) up to the last dose of IL-2 + 30 days.

Time to Response for Evaluable Patients (SD or Better)

- DCR is: 80%
- Time to response is similar to Cohort 1



Of 10 patients in Efficacy Set, one patient (Patient 10) is not evaluable (NE) due to melanoma-related death prior to first tumor assessment not represented on figure.

Iovance C-144-01 Efficacy

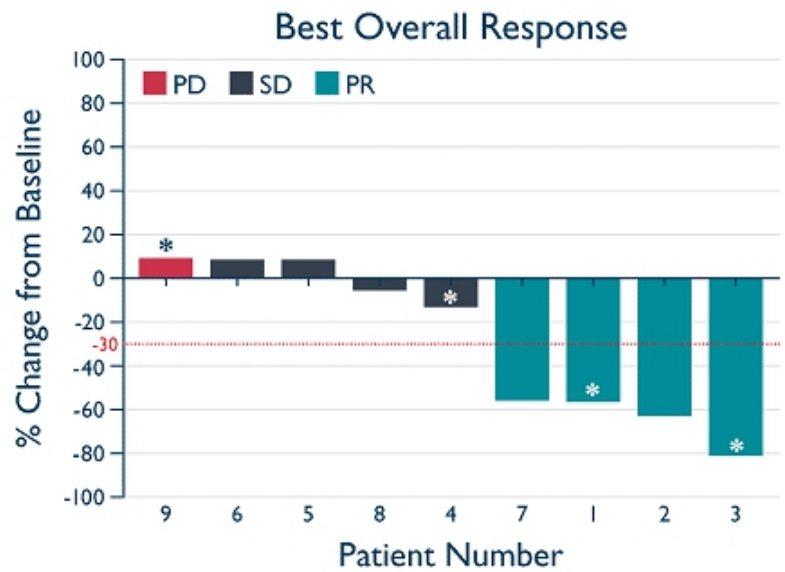
- Mean number of TIL cells infused:
 34×10^9
- Median number of IL-2 doses administered was 4.5
- Patients with BRAF mutation responded as well as patients with wild type BRAF

One patient (Patient 10) had passed away prior to the first assessment (still considered in the Efficacy Set).

* Refers to patients with BRAF mutation

Abbreviations: PR, partial response; SD, stable disease, PD, progressive disease

17



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Iovance C-144-01 Efficacy: Evaluable Patient Data

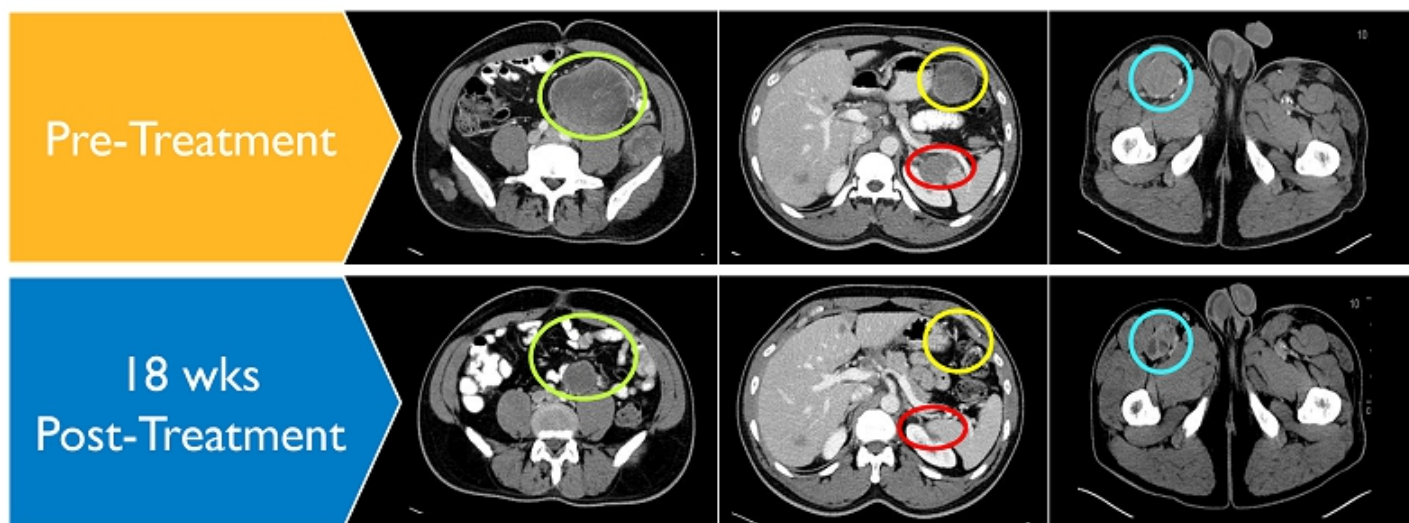
- All efficacy-evaluable patients had received an anti-PD-1 and anti-CTLA-4 checkpoint inhibitor

RESPONSE	PATIENTS, N=10 n (%)
Objective Response Rate	4 (40%)
Disease Control Rate	8 (80%)
Partial Response	4 (40%)
Stable Disease	4 (40%)
Progressive Disease	1 (10%)
Non-Evaluable*	1 (10%)

1 Dec 2017 Data Cut

* NE due to not reaching first assessment.

CT Scan for Patient with PR in C-144-01 Study



● TL1: Lt low. quad. abdom. - BL: 8.8 cm / 18 wk: 3.7 cm

● TL2: Lt uppr quad abdom. - BL: 5.2 cm / 18 wk: 0 cm

● TL5: Rt femoral LN - 4 cm (short axis) / 18 wk: 2.3 cm

● TL3: Lt renal - BL: 4.1 cm / 18 wk: 2.1 cm

Head & Neck Cancer

Head and Neck Squamous Cell Carcinoma (HNSCC)

HNSCC Cancer Facts^(1,2)



765k

New Cases WW
each year

303k

Deaths WW
each year



63k

Diagnoses in U.S.
each year

13k

Deaths in U.S.
each year

HNSCC

Well-suited for immunotherapy

ORR 13-16%

For population receiving immunotherapy (e.g, PD-1 inhibitors)

TIL

Prognostic value in HPV⁺ & HPV⁻ tumor specimens

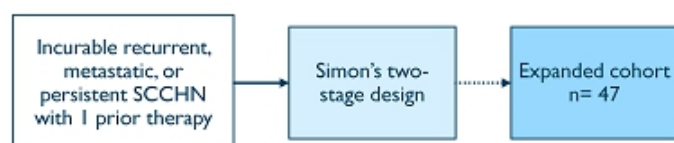
Abbreviations: HPV, human papillomavirus infection; OPC, oropharyngeal cancer; ORR, objective response rate; TIL, tumor infiltrating lymphocytes.

⁽¹⁾ Global Burden of Disease Cancer Collaboration, Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-years for 32 Cancer Groups, 1990 to 2015: A Systematic Analysis for the Global Burden of Disease Study. *JAMA Oncol.* 2017;3(4):524

⁽²⁾ <https://seer.cancer.gov/statfacts/html/oralcav.html> and <https://seer.cancer.gov/statfacts/html/laryn.html>

Iovance Phase 2 Trial in Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck (C-145-03)

Phase 2 study to evaluate the efficacy and safety of autologous Tumor Infiltrating Lymphocytes (LN-145) for the treatment of patients with recurrent metastatic squamous cell carcinoma of the head and neck (NCT03083873)



Key Inclusion Criteria:

- Measurable metastatic disease and ≥ 1 lesion resectable for TIL generation
- Relapsed or refractory recurrent metastatic squamous cell carcinoma of the head and neck and have received at least one prior systemic therapy
- Age ≥ 18
- ECOG PS 0-1

Endpoints:

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

Study Updates:

- N=47; Simon's two-stage design triggered

Iovance C-145-03 Phase 2 Trial in Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck: Preliminary Evidence of Efficacy

BASELINE DEMOGRAPHICS	PATIENTS, N=8 n (%)	SAFETY: TREATMENT EMERGENT ADVERSE EVENTS (≥30%) BY PREFERRED TERM	PATIENTS, N=8 n (%)
Prior therapies, n (%)		Pyrexia	7 (88)
Median prior therapies	4	Chills	6 (75)
Anti-PD-1	8 (100)	Hyponatremia	6 (75)
Anti-CTLA-4	2 (25)	Hypotension	6 (75)

Efficacy: 3 have PR (per RECIST 1.1) ORR = 38%

Abbreviations: ORR, objective response rate; PR, partial response.

Cervical Cancer

Cervical Cancer

Cervical Cancer Facts^(1,2)



765k

New Cases WW
each year

239k

Deaths WW
each year



13k

Diagnoses in U.S.
each year

4k

Deaths in U.S.
each year

Cervical Cancer

Well-suited for
immunotherapy

ORR 14.3%

For PD-L1 + patients
receiving immunotherapy

TIL

Prognostic value in
HPV+ tumor specimens

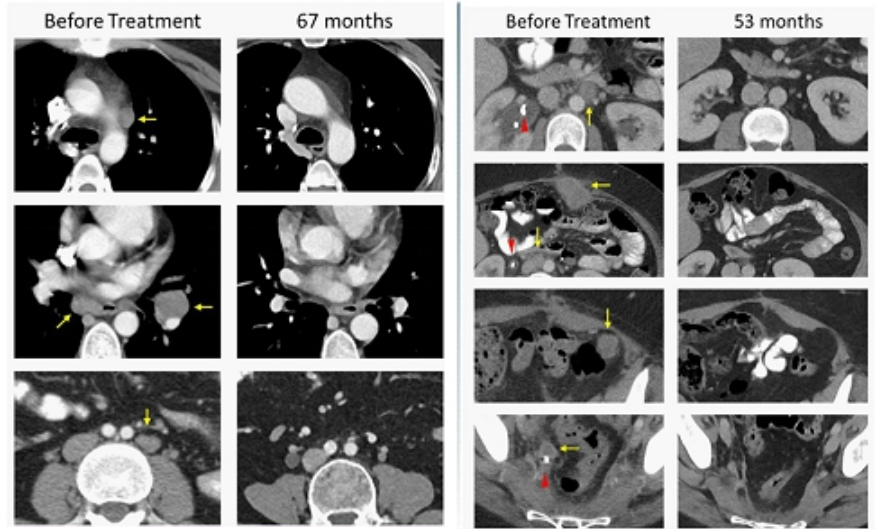
Abbreviations: HPV, human papillomavirus infection; ORR, objective response rate; TIL, tumor infiltrating lymphocytes.

⁽¹⁾ Global Burden of Disease Cancer Collaboration, Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-years for 32 Cancer Groups, 1990 to 2015: A Systematic Analysis for the Global Burden of Disease Study. *JAMA Oncol.* 2017;3(4):524

⁽²⁾ <https://seer.cancer.gov/statfacts/html/oralcav.html> and <https://seer.cancer.gov/statfacts/html/laryn.html>

NCI Cervical Cancer and TIL Treatment Data

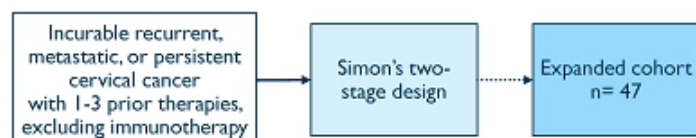
	PATIENTS (%)	DURATION (MONTHS)
Total	18 (100)	
PR	3 (17)	3
CR	2 (11)	53+, 67+
ORR	28%	



Stevanovic, et al., Treatment of Metastatic Human Papillomavirus-Associated Epithelial Cancers with Adoptive Transfer of Tumor-Infiltrating T Cells, ASCO 2018, Abstract #3004
 This type of response may not be representative of all patients.

Iovance Phase 2 Trial in Recurrent, Metastatic or Persistent Cervical Carcinoma (C-145-04)

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



Key Inclusion Criteria:

- Measurable recurrent, persistent, or metastatic disease and ≥ 1 lesion resectable for TIL generation
- One to three prior systemic therapies and either progressed or had no response on such therapies
- ECOG PS 0-1

Endpoints:

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

Key Updates:

- First patient dosed in U.S. in Sept. 2017
- Open to enrollment in Europe
- Of two evaluable cervical patients, one has a confirmed PR, one SD

Non-Small Cell Lung Cancer

Lung Cancer Has the Highest Mortality Rate Among Solid Tumors in the U.S.

INDICATION	NEW CASES ⁽¹⁾	DEATHS ⁽¹⁾
Melanoma	87,110	9,730
Cervix Uteri	12,820	4,210
Oral Cavity, Pharynx & Larynx	63,030	13,360
Lung & Bronchus	222,500	155,870
Bladder	79,030	16,870
Breast	252,710	40,610
Pancreatic	53,670	43,090
Brain & Other Nervous System	23,800	16,700

LUNG CANCER



222K

New cases in 2017

5YR SURVIVAL RATE⁽²⁾

<20% for NSCLC

⁽¹⁾ <https://seer.cancer.gov>

⁽²⁾ <https://seer.cancer.gov/statfacts/html/lungb.html>

Ongoing Collaborations and Partnerships

Two Ongoing Trials in Non-Small Cell Lung Cancer (NSCLC)

Moffitt Cancer Center sponsored trial

- TIL + anti-PD-1, nivolumab (Opdivo®)
- An Investigator Initiated Trial (IIT), Phase I study in 18 advanced NSCLC patients⁽¹⁾
- Early results to be presented at World Lung on September 24 in Toronto, *Safety and Clinical Activity of Adoptive Cell Transfer Using Tumor Infiltrating Lymphocytes (TIL) Combined with Nivolumab in NSCLC*



Iovance sponsored trial in collaboration with MedImmune / AstraZeneca

- TIL +/- anti-PD-L1, durvalumab:
- Iovance-sponsored, Phase 2, two-cohort clinical trial to anti-PD-1/PD-L1 naïve NSCLC



⁽¹⁾ A Stand Up to Cancer (SU2C) supported clinical trial. Additional collaborators include Bristol-Myers Squibb and Prometheus Inc.

Moffitt Phase 1 NSCLC Study

Phase I clinical trial combining nivolumab and Tumor Infiltrating Lymphocytes (TIL) for patients with advanced Non-Small Cell Lung Cancer (NCT03215810)

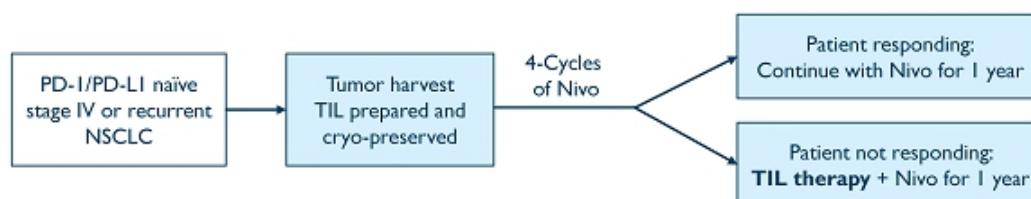
- N=18
- First patient harvested in 4Q 2017

Key Inclusion Criteria:

- PD-1/PD-L1 naïve
- Confirmed or suspected diagnosis of stage IV or recurrent NSCLC

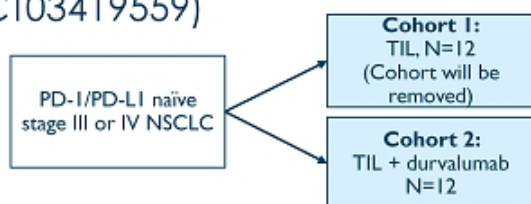
Endpoints:

- Primary: Safety
- Secondary: Efficacy (ORR and PFS)



Iovance-Sponsored NSCLC Phase 2 Study

A Phase 2 study (IOV-LUN-201) to assess the efficacy and safety of autologous Tumor Infiltrating Lymphocytes (LN-145) alone and in combination with anti-PD-L1 inhibitor durvalumab (MEDI4736) in patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) (NCT03419559)



Key Inclusion Criteria:

- Histologically and/or cytologically confirmed diagnosis of Stage III or Stage IV NSCLC
- ≥ 1 lesion resectable for TIL generation

Key Exclusion Criteria:

- Prior anti-PD-I or anti PD-LI use

Endpoints:

- Primary: Efficacy (ORR) and safety
- Secondary: Efficacy

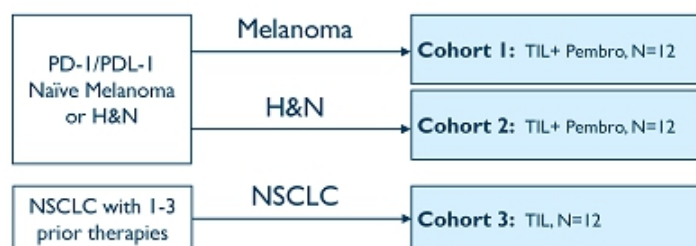


TIL in Combination with Standard of Care

Earlier Line of Therapy

IOV-COM-202: Co-Administration of TIL and Pembrolizumab

A Phase 2, multicenter study of autologous Tumor Infiltrating Lymphocytes (LN-144/LN-145) in patients with solid tumors (NCT0364592)



Key Inclusion Criteria:

- Histologically confirmed diagnosis of unresectable or metastatic melanoma, recurrent or metastatic squamous cell carcinoma of the head and neck, or recurrent or metastatic NSCLC
- ≥ 1 lesion resectable for TIL generation

Key Exclusion Criteria:

- Cohorts 1 and 2: No prior anti-PD-1 or anti-PD-L1 use
- Cohort 3: 1-3 prior systemic anticancer therapies

Endpoints:

- Primary: Efficacy (ORR) and safety
- Secondary: Efficacy

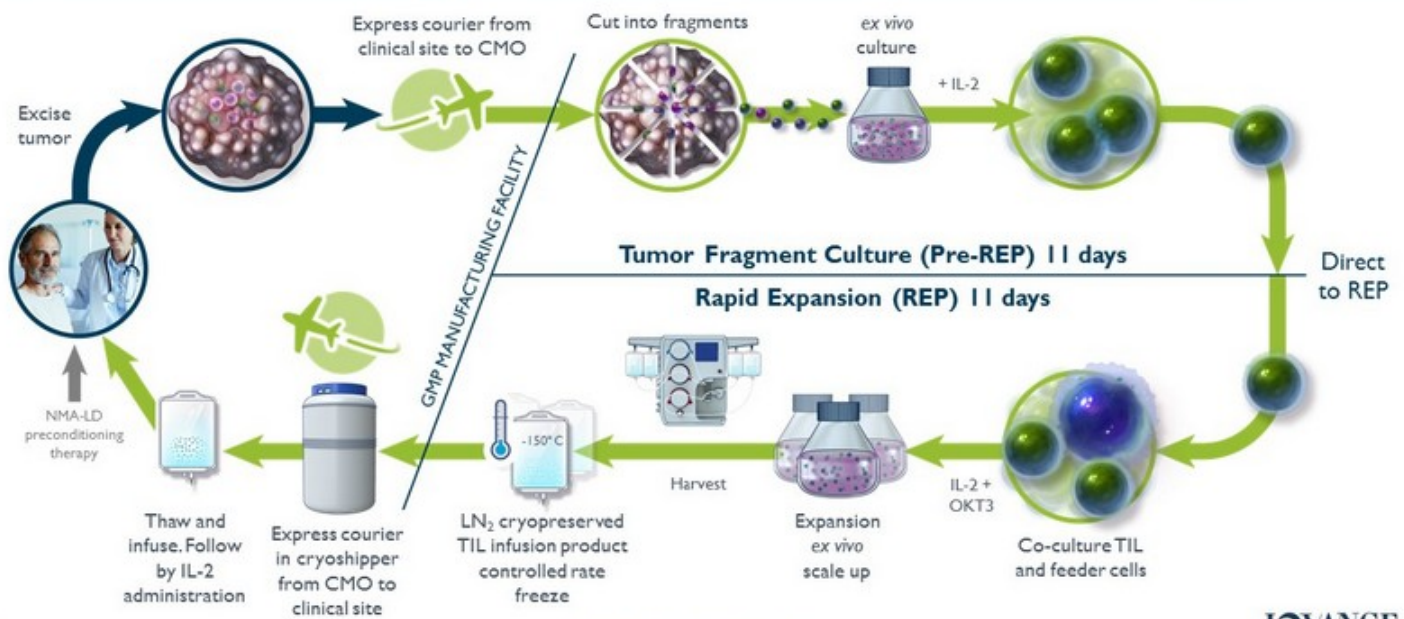
Research

Iovance TIL Research Focus

1. Expand the TIL platform into new indications
 - Heme indication (OSU collaboration)
 - Bladder cancer (Roswell Park Cancer Institute)
2. Prepare or select more potent TIL
 - Use anti-4-1BB, anti-OX40, or IL-2/ IL-15/ IL-21 cocktails in *ex vivo* growth of TIL
 - License to uses of 4-1BB agonists obtained from Moffitt Cancer Center
 - Select more potent TIL such as high PD1 expression
3. Genetically modify to make a more tumor-reactive TIL
 - Collectis TALEN® collaboration
 - RXi RNAi collaboration
4. Identify biomarkers to find a better TIL product or better patient population

Manufacturing

Iovance Cryopreserved 22 Day TIL Manufacturing Process- US; Wuxi, EU: Lonza



Corporate

Financial Summary June 30, 2018 (unaudited)

	IN MILLIONS
Common shares outstanding	93
Preferred shares	7 ⁽¹⁾
Warrants/options/RSU's	10
Cash, cash equivalents, short-term investments	\$276
Debt	\$0

⁽¹⁾ Preferred shares are shown on an as-converted basis.

Summary of Recent Accomplishments

- Built a broad TIL clinical development program - entered new indications and announced new collaborations
 - 70 clinical sites now active across five IOVA studies
 - Data in melanoma trial with preliminary results indicating clinically meaningful benefit in patients with relapsed/refractory disease
 - Cervical and head and neck studies ongoing
 - TIL is going to be investigated in NSCLC in combination in earlier lines of therapies
 - Moving to earlier line of therapy with activation of Basket Study
 - Two studies in MD Anderson collaboration are enrolling in sarcomas, ovarian and pancreatic cancers
- Streamlining manufacturing
 - Capacity fully established in U.S. and EU
 - Developed shorter duration Gen 2 for all future TIL therapy development and commercialization
- Building IP
 - A broad portfolio of immuno-oncology patent applications including coverage for Gen 2 manufacturing

Key Anticipated 2018 Milestones

MANUFACTURING

- ✓ Transition all trials over to Gen 2 manufacturing process
- ✓ Start up in manufacturing and clinical trials in Europe
- Optimization of the process in anticipation of commercialization

CLINICAL

- ✓ Continue enrollment into the melanoma program
- ✓ Continue to advance head & neck, cervical, and NSCLC
- ✓ Pursue new indications
 - ✓ Ovarian, Sarcomas
- Actively move TIL therapy to earlier line of treatment
 - IOV-COM-202
- Present data from melanoma and at least one other indication at 2018 medical meetings
 - ✓ NSCLC

REGULATORY

- ✓ Activate melanoma and cervical studies in Europe in 1H 2018
- FDA interaction to define the registration path for LN-144 (lifileucel)

PARTNERSHIPS

- ✓ Partner with our suppliers and vendors, as well as technology providers
 - ✓ Organizations with technologies for genetic modification
- ✓ Continue collaborating with new clinical sites and hospitals to assure preparation for commercialization
 - ✓ 70 Clinical sites active across four studies
 - ✓ Roswell Park



IOVANCE
BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY

Thank you

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