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): December 13, 2017

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.

A copy of the presentation to be presented on December 13, 2017 by Iovance Biotherapeutics, Inc. at its Analyst Day event, describing its progress in clinical development, manufacturing, and intellectual property, is attached as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements And Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Iovance Biotherapeutics, Inc., Analyst Presentation-December 2017.

SIGNATURES

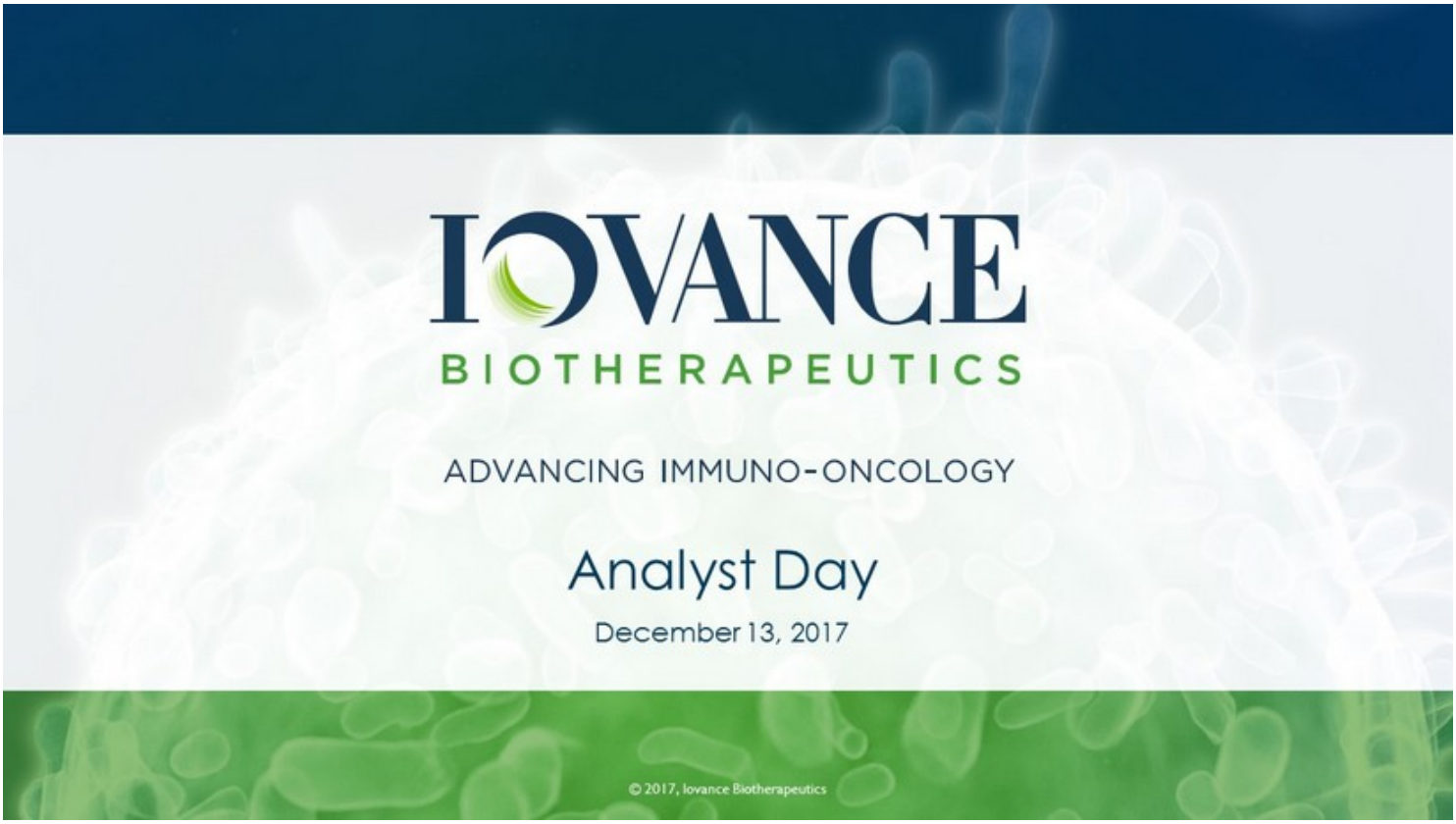
Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 13, 2017

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1


IOVANCE
BIOTHERAPEUTICS
ADVANCING IMMUNO-ONCOLOGY
Analyst Day
December 13, 2017
© 2017, Iovance Biotherapeutics

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.

Today's Agenda

Iovance Corporate and Clinical Overview

START	END	AGENDA ITEM	DURATION	DISCUSSANT
8:30am	9:00	• Breakfast and registration	*30 min*	
9:00	9:15	• Welcome • TIL therapy overview • Selection of Gen 2	*15 min*	Dr. Maria Fardis
9:15	9:30	• Manufacturing Update-Gen 2	*15 min*	Mr. Rich Gaeto
9:30	9:50	• Clinical overview • Review of Melanoma data	*20 min*	Dr. Igor Gorbatchevsky
9:50	10:15	• Clinical program, expansion into lung cancer, MD Anderson collaboration • Upcoming milestones	*25 min*	Dr. Maria Fardis
10:15	10:30	• Q&A	*15 min*	
10:30	10:40	• Break	*10 min*	

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

Competitive Advantages of TIL in Solid Tumors

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

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 and cervical cancers
Long maintenance period	One-time treatment	One-time treatment	One-time treatment
No genetic modification	Genetic modification	Genetic modification	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

IOVANCE BIOTHERAPEUTICS

US Cancer Statistics

ESTIMATED NEW CASES 2017

1,688K*

ESTIMATED DEATHS 2017

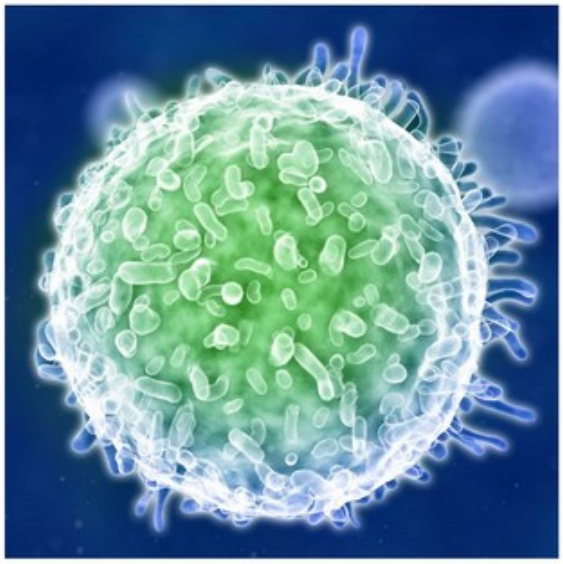
601K*

*https://seer.cancer.gov/statfacts/html/all.html

IOVANCE BIOTHERAPEUTICS

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

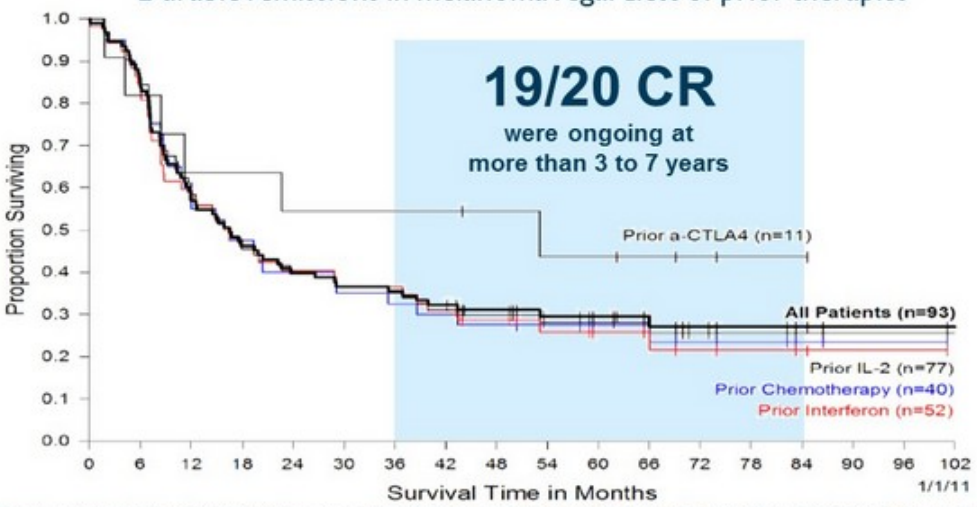
- Leverages and enhances the body's natural defense against cancer using a patient's own TIL
- Polyclonal and can recognize multiple neoantigens
  - Solid tumors are heterogeneous
- Durable response with one-time treatment
  - Potential to establish immunological memory, requiring no additional maintenance therapy after infusion
  - Responses seen both in treatment naïve and refractory melanoma patients who have failed other options, including checkpoint inhibitors



IOVANCE BIOTHERAPEUTICS

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)

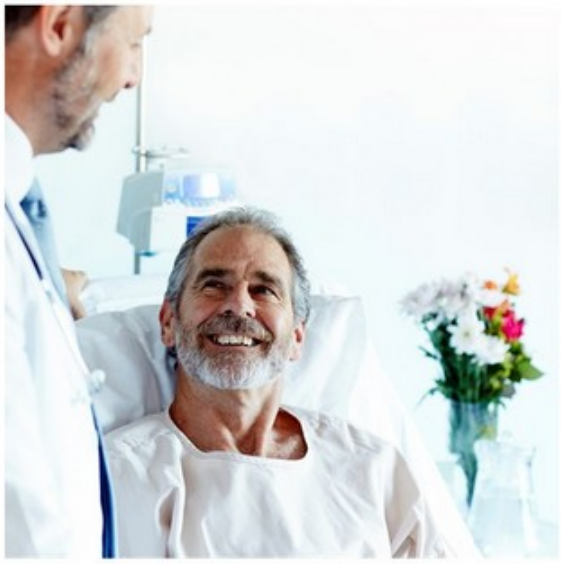
ORR 56%

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.

TIL Therapy: Single Treatment, High Response Rate

- TIL therapy has demonstrated efficacy in melanoma and cervical cancers
- Single treatment has led to durable CRs, lasting multiple years, in patients without exposure to checkpoints
- Proven to work in solid tumors at multiple academic institutions as well as the NCI



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.
Stevanovic et al., *Science*, 2017, (356), 200.
Data from third parties may not be representative of Iovance's data.

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Iovance Biotherapeutics Today

- Iovance Biotherapeutics has a license to the TIL technology from the NCI
- Iovance has approximately ~70 employees
- The company is headquartered in San Carlos, CA with offices in New York City, Tampa, and a subsidiary in Europe

2017 Iovance Accomplishments

- ✓Establishment of manufacturing capacity
- ✓Developing a new, shorter manufacturing process, establish novel IP
  - ✓Generation 2 of manufacturing was developed at Iovance, tech transferred to our CMOs and dosed in patients
  - ✓Based on clinical data, this method has been selected for current and future clinical trials and commercialization
- ✓Building global clinical trials investigating multiple indications
  - ✓Two clinical studies are expected to be activated in Europe in 2018
  - ✓Explore multiple indications internally (melanoma, cervical, head and neck, and now, non-small cell lung cancer), and collaborate for new indications (sarcomas, ovarian, pancreatic)
- ✓Work with partners to expand the pipeline: MedImmune/AstraZeneca, MD Anderson, Moffitt
- ✓Initiate discussions with US and EU agencies toward registration of TIL toward a label
  - ✓Fast track
  - ✓CTA submissions

TIL Therapy Manufacturing

- Clinical and commercial manufacturing capabilities are in place in the US and EU
  - US: Lonza, WuXi (multiple locations), Moffitt
  - EU: LonzaNL (formerly PharmaCell)
- Shorter Generation 2 manufacturing process has been selected for all current and future Iovance studies (all protocols amended)
  - Shortens the time patients will receive their TIL product
  - Allows flexibility in scheduling of treatment dosing at infusion center
  - Reduces cost of manufacturing by ~35% vs Gen 1
- WuXi Phase 3 clinical and commercial suite is being used for manufacturing the Gen 2 product

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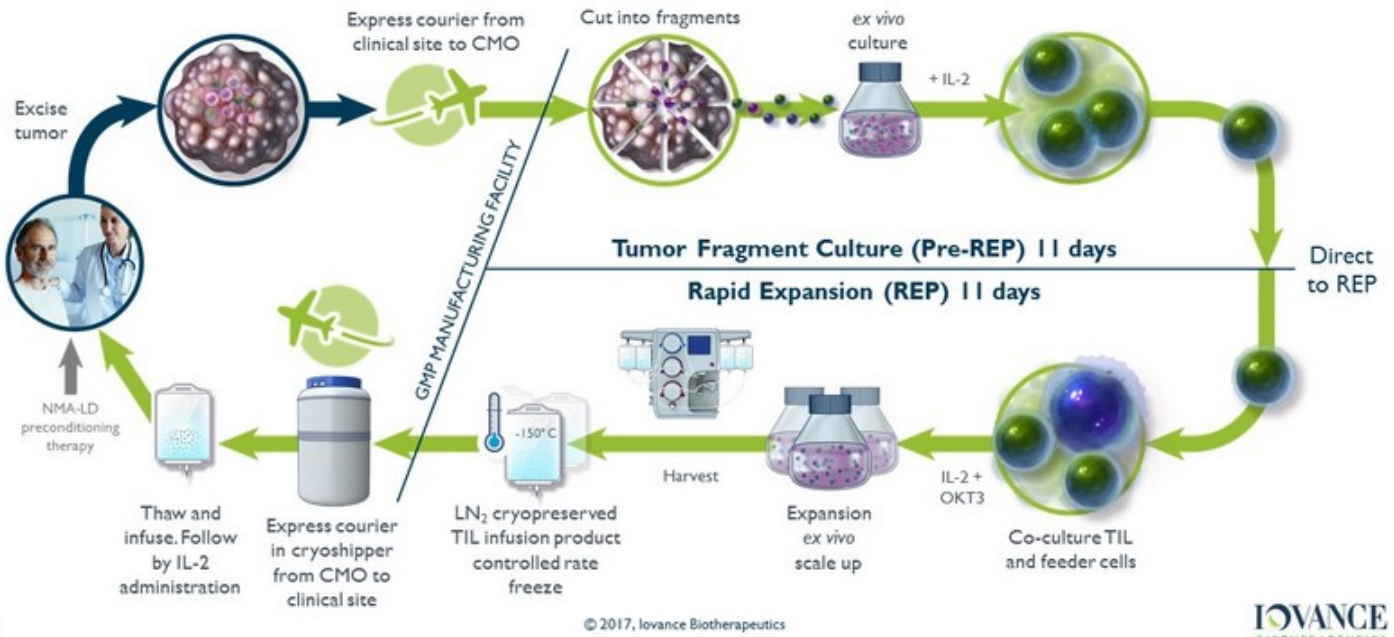
Manufacturing

Iovance Cryopreserved LN-144 and LN-145 Manufacturing Process (22 days)



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Gen 2 Process Improvements

PROCESS STEP	GEN 1	GEN 2	Advantages
Fragment Culture	≤21 days, multiple bioreactors, operator interventions	11 days, single closed bioreactor, minimal intervention	Shortens culture, reduces interventions, amenable to automation
TIL selection	IL-2 expanded TIL cryopreserved in-process, tested, selection based on phenotype	Bulk TIL direct to co-culture	Shorten process by allowing increased seeding of co-culture, increases clonal diversity, reduces steps
Rapid Expansion	REP Duration: 16-17 days	REP Duration: 11 days	Reduces operator interventions, shortens process, amenable to automation
Harvest/Wash	Manual volume reduction and harvest. Manual wash and concentration by centrifugation.	Closed semi-automated volume reduction and harvest. Automated wash and concentration.	Reduces operator interventions, automated, maintains closed system
Formulation	Fresh hypothermic product (2- 8^{0}C)	Cryopreserved product (≤ -150^{0}C)	Allows for global trials through increased shipping flexibility, flexible in patient scheduling
Manufacturing Time	5.5- 6 weeks process time	22 day process time	Decreased turnaround to patient, greater clean room throughput, lower cost of goods

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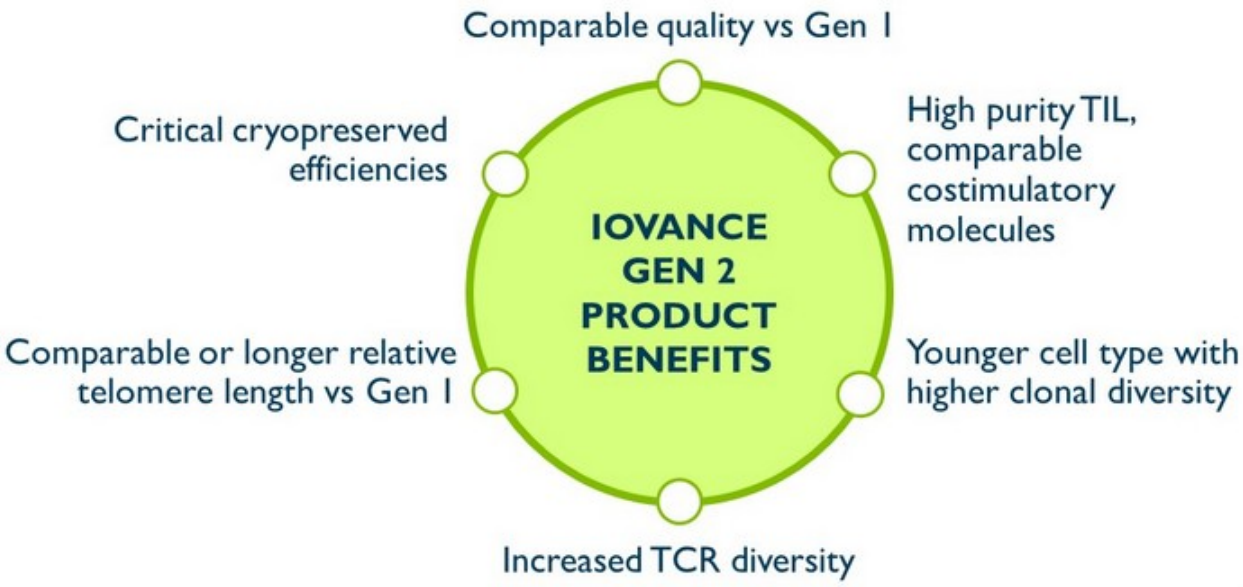
Iovance Generation 2 (Gen 2) TIL Infusion Product Benefits vs Generation 1 (Gen 1)



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Gen 2 Intellectual Property

- Iovance has a broad TIL-based patent portfolio
  - Advances in TIL manufacturing implemented in the Gen 2 process
- Multiple provisional patent applications have been filed
- Worldwide rights will be pursued under the PCT path and US rights will be pursued through an expedited process
- If granted, the patent application would provide exclusive rights that extend through 2038

Cell Orchestration Platform (TrakCel Collaboration)

Logistics of Each Patient's Sample and TIL Therapy

An automated process integrating scheduling, capacity and logistics throughout the supply chain: Part 11 compliant, improves communication across the stakeholders

1. EXCISE
2. EXTRACT
3. EXPAND
4. PREPARE & INFUSE

Legend:
- Clinic
- Iovance CMO GMP Facility

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Clinical Development

Iovance Clinical Pipeline

INDICATION	REGIMEN	N	PARTNER	PRECLINICAL	PHASE 1	PHASE 2
Melanoma	TIL LN-144	60	—			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			Phase 2 trials to initiate in 2018

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Melanoma

Metastatic Melanoma (MM)

Melanoma Cancer Facts[1,2]

>352K **New cases WW** each year	**>60k** **Deaths WW** each year
87k **Diagnoses in U.S.** in 2017	**10k** **Deaths in U.S.** in 2017

MM
Well-suited for immunotherapy

ORR 33-35%
For first line MM receiving immunotherapy (e.g. single agent PD-1 inhibitors)

TIL ORR: 56%
For PD-1/PDL-1 first and second line MM

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

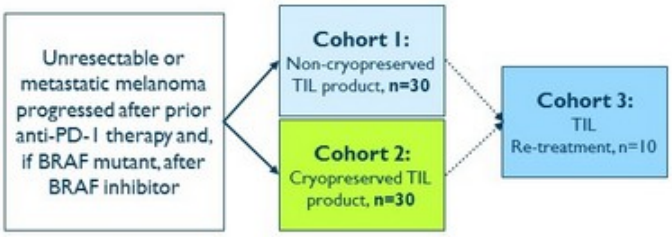
[2] https://seer.cancer.gov/statfacts/html/melan.html

IOVANCE BIOTHERAPEUTICS

CURRENTLY ENROLLING

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

A 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

Treatment Cohorts:

1. Non-cryopreserved LN-144 product
2. Cryopreserved LN-144 product
3. Retreatment with LN-144 for patients without response or who progress after initial response

Endpoints:

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

IOVANCE BIOTHERAPEUTICS

COHORT 2

Patient Characteristics from Cohort 2 Update

CHARACTERISTIC	Cohort 2 N=17, (%)
Gender, n (%)	
Male	8 (47)
Female	9 (53)
Age	
Median	54
Min, Max	35, 66
Prior therapies, n (%)	
Mean # prior systemic therapies	3.6
Anti-CTLA-4	15 (88)
Anti-PD-1	16 (94)
Target Lesion Sum of Diameter (mm)	
Mean (SD)	140 (93)
Min, Max	38, 342

CHARACTERISTIC	Cohort 2 N=17, (%)
Baseline ECOG score, n (%)	
0	11 (65)
1	6 (35)
BRAF Status, n (%)	
Mutated	5 (29)
Wild Type	9 (53)
Unknown	3 (18)
Baseline LDH (U/L [SD])	
1-2 times ULN	8 (47)
> 2 times ULN	2 (12)
Number of Target & Non-Target Lesions (at Base Line)	
>3	12 (71)
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

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COHORT 2

Treatment Emergent Adverse Events (≥ 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.

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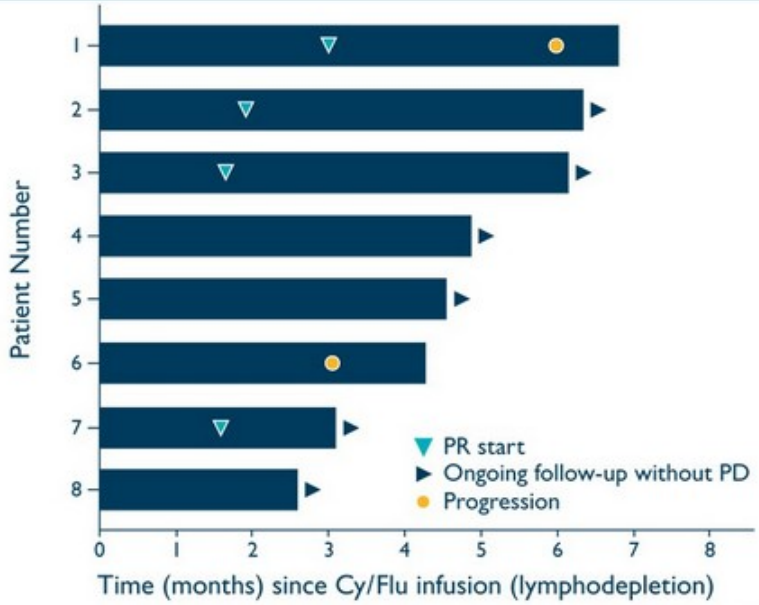
COHORT 2

Time to Response for Evaluable Patients (SD or Better)

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



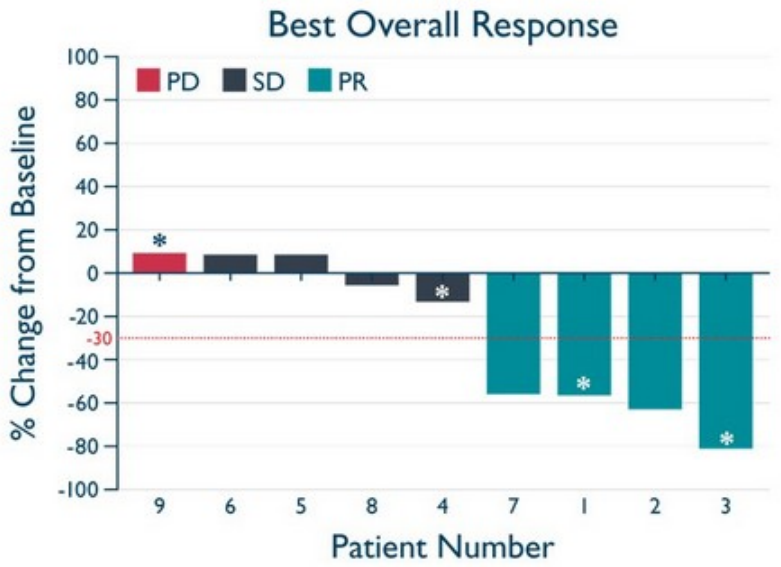
Of 10 patients in Efficacy Set, one patient (Patient 10) is not evaluable (NE) due to melanoma-related death prior to first tumor assessment not represented on figure.

IOVANCE BIOTHERAPEUTICS

COHORT 2

Iovance C-144-01 Efficacy

- Mean number of TIL cells infused: 34 x 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

IOVANCE BIOTHERAPEUTICS

COHORT 2

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.

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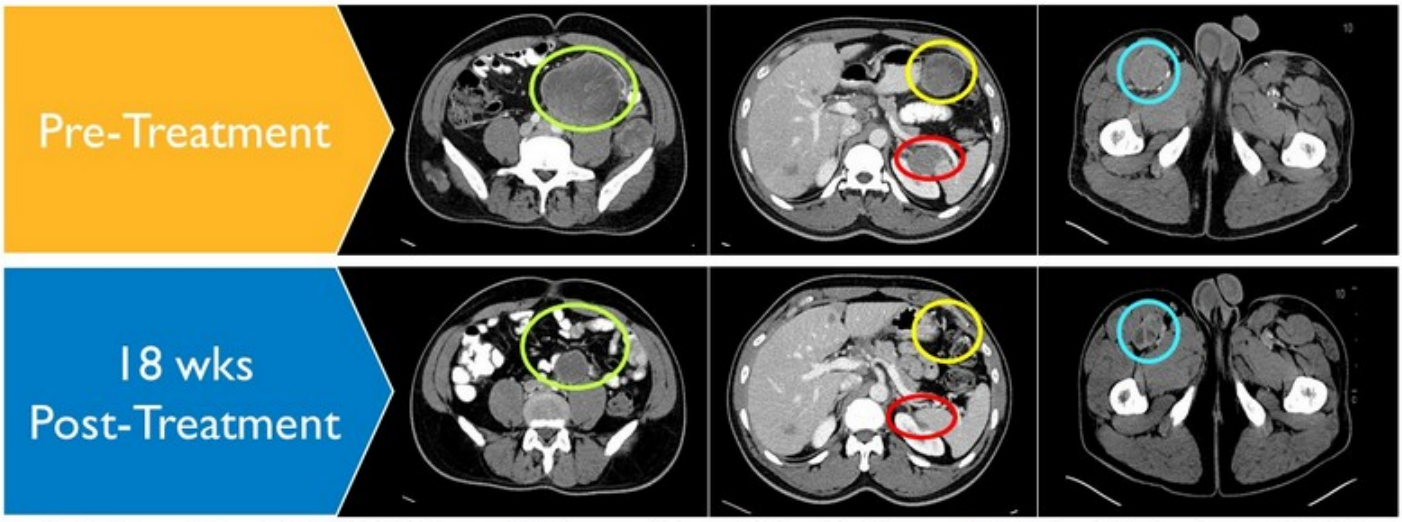
CT Scan for Patient with PR



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

TL3: Lt renal – BL: 4.1 cm / 18 wk: 2.1 cm

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

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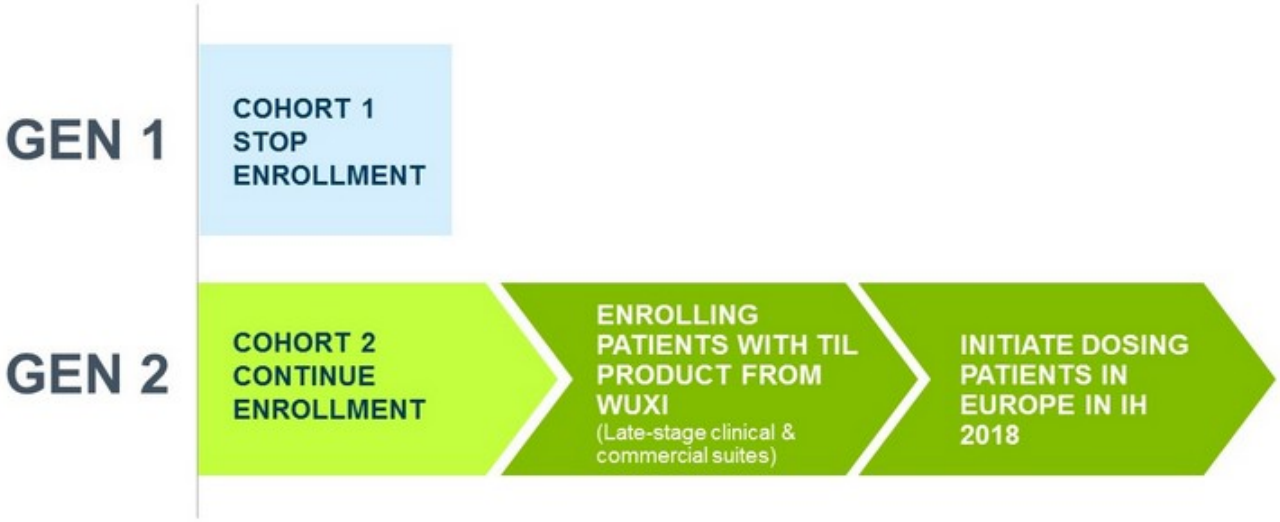
Future Plan for the Study



IOVANCE BIOTHERAPEUTICS

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 BIOTHERAPEUTICS

CURRENTLY ENROLLING

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

A 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)

N=47; Simon's two-stage design

Gen 2 manufacturing will be used going forward

Key Inclusion Criteria:

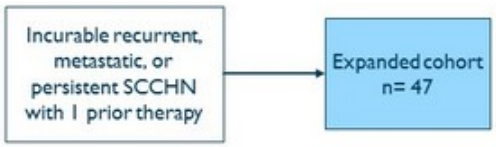
- Measurable metastatic disease and ≥ 1 lesion resectable for TIL generation
- Relapsed or refractory recurrent and/or metastatic carcinoma of the head and neck and have received at least one prior systemic therapy
- Age ≥ 18
- ECOG PS 0-1

Endpoints:

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

LN-145 for Head & Neck: Stage 2 of Enrollment Was Triggered for Ongoing Trial

- The study will proceed with enrollment to full 47 patients
- Preliminary data anticipated at an upcoming scientific conference in 2018



N=47; Simon's two-stage design

LN-145: protocol was amended to continue enrollment with Gen 2 product

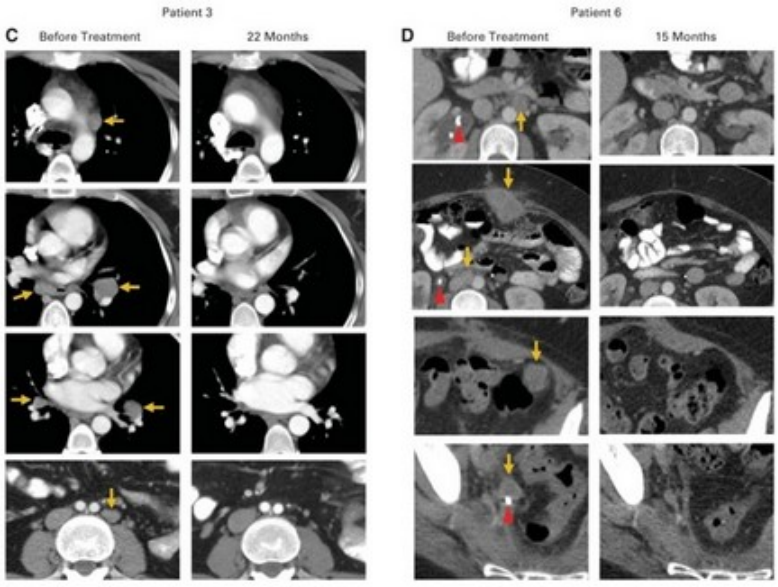
Endpoints:

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

Cervical Cancer

NCI Cervical Cancer and TIL Treatment Data

	PATIENTS (%)	DURATION (MONTHS)
Total	9 (100)	
PR	1 (11)	3
CR	2 (22)	54+, 46+



Stevanovic, et al. Complete Regression of Metastatic Cervical Cancer After Treatment with Human Papillomavirus-Targeted Tumor-Infiltrating T Cells, *J Clin Oncol* 2015, 33 (14), 1543.
Hinrichs, et al. HPV-targeted Tumor-Infiltrating Lymphocytes for Cervical Cancer, *J Clin Oncol*, 2014, 23, 5s.
Stevanovic et al., *Science*, 2017, (356), 200.
This type of response may not be representative of all patients.

IOVANCE BIOTHERAPEUTICS

CURRENTLY ENROLLING

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

A Phase 2, Multicenter Study to Evaluate the Efficacy and Safety Using Autologous Tumor Infiltrating Lymphocytes (LN-145) in Patients with Recurrent, Metastatic or Persistent Cervical Carcinoma (NCT03108495)

N=47; Simon's two-stage design

LN-145, protocol was amended to continue enrollment with Gen-2 product

Study will begin enrolling in Europe in 2018

Key Inclusion Criteria:

- Measurable recurrent, persistent, or metastatic disease and ≥ 1 lesion resectable for TIL generation
- At least one prior systemic therapy and either progressed or had no response on such therapy
- Age ≥ 18
- ECOG PS 0-1

Endpoints:

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

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Non-Small Cell Lung Cancer

Market Opportunity for TIL Therapy in US

INDICATION	NEW CASES[1]	DEATHS
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

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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 1 study with advanced NSCLC patients[1]

MOFFITT CANCER CENTER

STAND UP TO CANCER

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 patients

MedImmune

AstraZeneca

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

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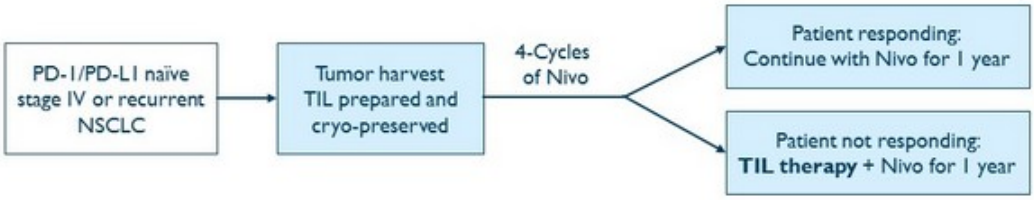
Moffitt Lung Study

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)



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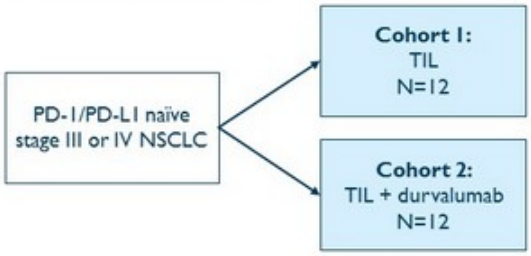
NSCLC Phase 2 Study

Expected start: 1H 2018

A Phase 2 Study 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)



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-1 or anti PD-L1 use

Endpoints:

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

MedImmune

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Sarcoma and Platinum-Resistant Ovarian Cancers

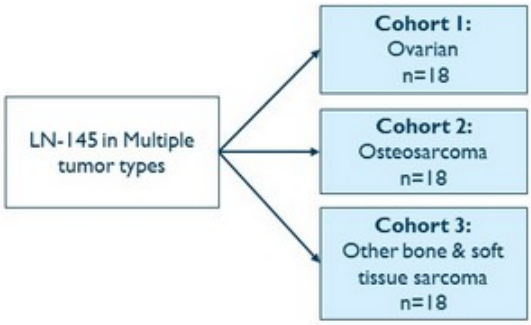
MD Anderson Collaboration Program Update

- Iovance has a collaboration with MD Anderson involving
  - Preclinical research in expanding understanding of TIL
  - Two clinical studies:
    1. LN-145 being provided by Iovance
       - Indications: sarcoma, platinum-resistant ovarian cancer
    2. TIL being manufactured by MDA manufacturing method (co-stimulants used ex vivo to expand growth of TIL)
  - Access to certain IP related to the method of manufacturing from MDA

MD Anderson Cancer Network™

MD Anderson Collaboration Program Update Clinical Study with LN-145

- Simon's two-stage design
- Expected first patient dosing in 1H 2018
- Iovance has capacity to support enrollment in this study.
- Gen 2 manufacturing process will be used



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Iovance Collaboration Pipeline

INDICATION	REGIMEN	N	PARTNER	PRECLINICAL	PHASE I	PHASE 2
Melanoma	Combination TIL ± TBI	101	NIH National Cancer Institute			Trial completed, 56% ORR, 24% CR
Melanoma	Combination TIL + Yervoy		Moffitt Cancer Center			Trial completed, publishing results
Melanoma	Combination TIL + Keytruda	170	NIH National Cancer Institute			Enrolling
Melanoma	Combination TIL + Opdivo	12	Moffitt Cancer Center		Enrolling	
Ocular (Uveal) Melanoma	TIL	23	NIH National Cancer Institute			
Glioblastoma	TIL		Karolinska Institutet			
Pancreatic Cancer	TIL		Karolinska Institutet			
Ovarian, Sarcomas, Pancreatic	TIL		MD Anderson Cancer Network			Phase 2 trials to initiate in 2018
Non-small cell lung cancer	Combination TIL + Opdivo	18	Moffitt Cancer Center		Enrolling	

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Future Indications

Hematologic Malignancies

- Iovance has produced data demonstrating
  - TIL can be grown from lymphoma with similar therapeutic potential as melanoma
- Collaboration with Ohio State University to investigate power of TIL therapy in heme
  - In patients with prior ibrutinib therapy
  - Sources for collection of tissue for TIL generation:
    - Blood
    - Marrow infiltrating lymphocytes

Summary of Recent Progress

- Manufacturing:
  - Gen 2 was selected for all future TIL therapy at Iovance
- IP:
  - A broad portfolio of immuno-oncology patent applications including coverage for Gen 2 manufacturing
- Clinical:
  - Updated data in melanoma trial was provided
    - Preliminary results indicate clinically meaningful benefit in patients with multiply relapsed/refractory disease
    - Treatment was well tolerated with manageable adverse events
    - Gen 2 cryopreserved TIL product, LN-144, is a viable therapeutic option for post-PD-1 metastatic melanoma patients
  - Cervical and head and neck studies are progressing well. Both studies will be utilizing Gen 2 product for patient dosing
  - TIL will be investigated in NSCLC
    - New indication
    - Moving to earlier line of therapy for TIL
  - MDA collaboration is underway for sarcomas and ovarian cancer

Key Anticipated Milestones

MANUFACTURING

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

CLINICAL

- Continue enrollment into the melanoma program
- Continue pursuit of the existing and new indications
- Actively move the TIL therapy to earlier line of treatment
- Present data from melanoma and at least one other indication at 2018 medical meetings

REGULATORY

- FDA interaction to define the registration path for LN-144
- Activate melanoma and cervical studies in Europe

PARTNERSHIPS

- Partner with our suppliers and vendors
- Continue collaborating with new clinical sites and hospitals to assure preparation for commercialization

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ADVANCING IMMUNO-ONCOLOGY

Thank you