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): May 13, 2022

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.)**
825 Industrial Road, Suite 400 **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 May 13, 2022, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Iovance Biotherapeutics, Inc., Corporate Presentation – May 2022.
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

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: May 13, 2022

IOVANCE BIOTHERAPEUTICS, INC.

By: /s/ Frederick G. Vogt
Frederick G. Vogt, Interim CEO & General Counsel

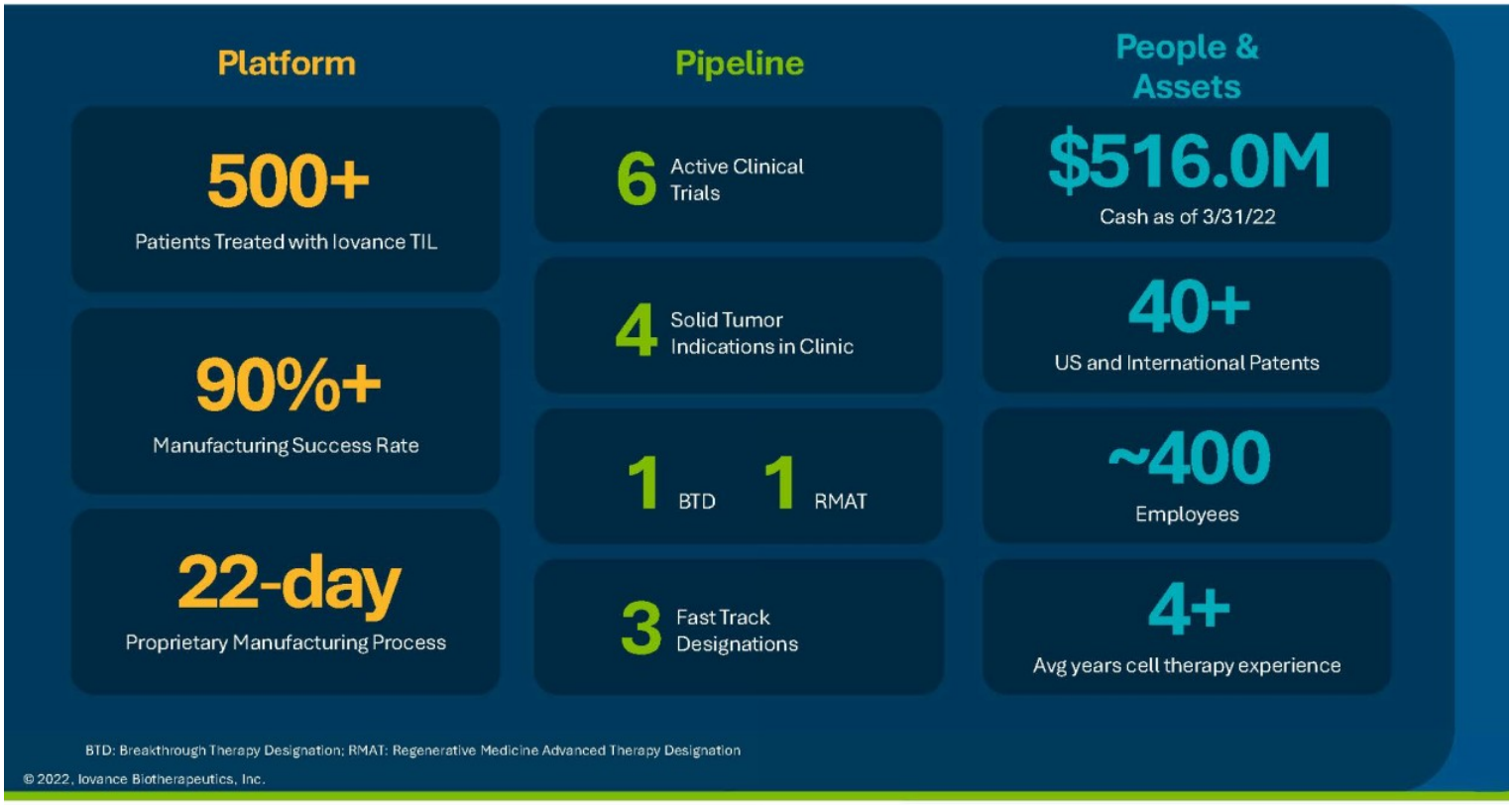
Exhibit 99.1


IOVANCE
BIOTHERAPEUTICS
Corporate Overview
May 2022
ADVANCING IMMUNO-ONCOLOGY
© 2022, Iovance Biotherapeutics, Inc.

Forward-Looking Statements

Certain matters discussed in this presentation are "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "
within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). All such written or oral statements made in this presentation, other th
historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by the PSLRA. With
foregoing, we may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "
"guidance," "outlook," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes and are intended to ident
statements. Forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historica
conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the
release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-look
not guarantees of future performance and are subject to risks, uncertainties and other factors, many of which are outside of our control, that may cause actua
activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements. Im
could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "R
filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and includ
limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the effects of the COVID-19 pandemic; risks relate
our ability to successfully develop, submit, obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other a
to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA approval; preliminary and interim d
may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgro
trials or in prior trials or cohorts; the risk that enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulat
changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; the risk that we may be required to conduct additional
modify ongoing or future clinical trials based on feedback from the FDA or other regulatory authorities; the risk that our interpretation of the results of our clini
communications with the FDA may differ from the interpretation of such results or communications by the FDA; the acceptance by the market of our product
potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may ac
potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored tr
unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; and other factors, inclu
economic conditions and regulatory developments, not within our control.

Global Leadership in Innovating, Developing and Delivering TIL Therapy for Patients with Cancer



BTD: Breakthrough Therapy Designation; RMAT: Regenerative Medicine Advanced Therapy Designation

Iovance Immuno-Oncology Pipeline

	PRODUCT CANDIDATE	INDICATION(S)	IND-ENABLING	PHASE 1	PHASE 2
TIL	Lifileucel/LN-144	Melanoma (post-anti-PD-1)	C-144-01 Study, Cohorts 2 & 4		
	Lifileucel	Cervical cancer (post-chemo; post-chemo & post-anti-PD-1)	C-145-04 Study, Cohorts 1 & 2		
	LN-145	NSCLC (2L post-chemo & post-anti-PD-1)	IOV-LUN-202 Study, Cohorts 1 & 2		
	LN-145	NSCLC (2-4L incl. post-anti-PD-1)	IOV-COM-202 Study, Cohort 3B		
	LN-145	HNSCC (post-anti-PD-1)	C-145-03 Study, Cohort 2		
TIL Combinations	Lifileucel + pembro	Melanoma (anti-PD-1 naïve)	IOV-COM-202 Study, Cohort 1A		
	Lifileucel + pembro	Cervical cancer (1L, chemo & anti-PD-1 naïve)	C-145-04 Study, Cohort 3		
	LN-145 + pembro	NSCLC (anti-PD-1 naïve)	IOV-COM-202 Study, Cohort 3A		
	LN-145 + ipi/nivo	NSCLC (post-anti-PD-1)	IOV-COM-202 Study, Cohort 3C		
	LN-145 + pembro	HNSCC (anti-PD-1 naïve)	IOV-COM-202 Study, Cohort 2A		
PD-1 Selected TIL	LN-145-S1	Melanoma (post-anti-PD-1)	IOV-COM-202 Study, Cohort 1B		
	LN-145-S1	HNSCC (post-anti-PD-1)	C-145-03 Study, Cohort 4		
Third-Generation (Gen 3) TIL 16-day manufacturing	LN-145 Gen 3 + core biopsy	NSCLC (2L post-chemo & post-anti-PD-1)	IOV-LUN-202 Study, Cohort 3		
	LN-144 Gen 3	Melanoma (post-anti-PD-1)	IOV-COM-202 Study, Cohort 1C		
	LN-145 Gen 3	HNSCC (post-anti-PD-1)	C-145-03 Study, Cohort 3		
PBL Therapy	IOV-2001	CLL/SLL (post-BTKi)	IOV-CLL-01 Study		
PD-1 Inactivated TIL	IOV-4001	Multiple	IND Allowance		
IL-2 Analog	IOV-3001	Multiple			

Abbreviations: BTD=breakthrough therapy designation; BTKi=Bruton's tyrosine kinase inhibitor; CLL/SLL=chronic lymphocytic leukemia and small lymphocytic lymphoma; HNSCC=head and neck squamous cell carcinoma; IL-2=interleukin 2; IND=investigational new drug; ipi/nivo=ipilimumab/nivolumab; NSCLC=non-small cell lung cancer; PBL=peripheral blood lymphocytes; RMAT=Regenerative Medicines Advanced Therapy; TIL=tumor infiltrating lymphocytes

Significant Market Potential in Solid Tumors

90%

of all cancer cases are solid tumors[1]

1.6M

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

Move into earlier line of therapy

Expand into other indications

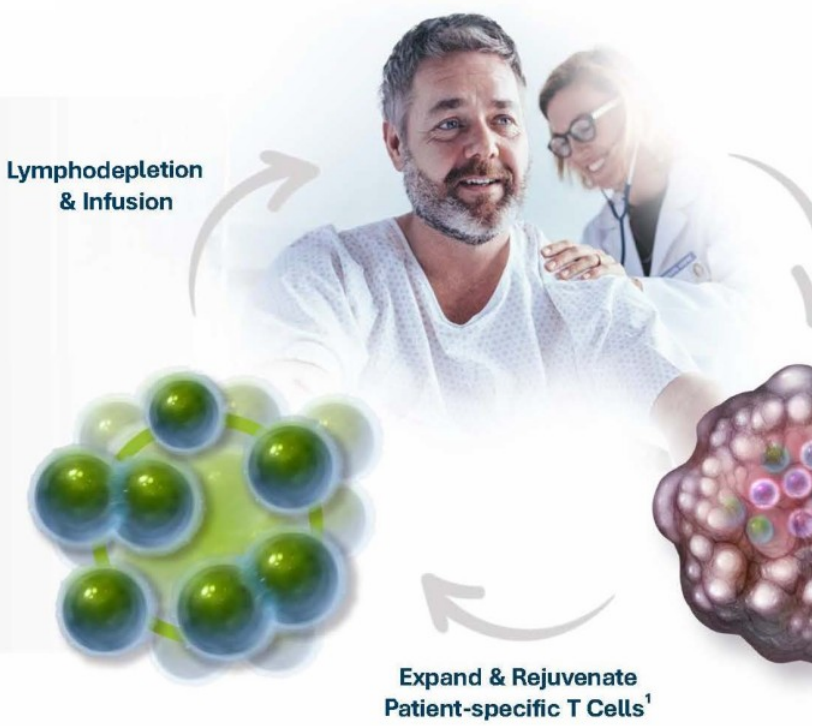
	Deaths[1]	Ne
Melanoma	7,180	
Cervical	4,290	
Lung & Bronchus	131,880	
Oral Cavity, Pharynx & Larynx	14,620	
Breast	43,600	
Pancreatic	48,220	
Brain & Other Nervous System	18,600	
	Potential to address unmet need in late lines of treatment	**Pote for e co stan**

1. https://seer.cancer.gov accessed February 2022

Tumor Infiltrating Lymphocytes (TIL): Leading Platform for Treatment of Solid Tumors

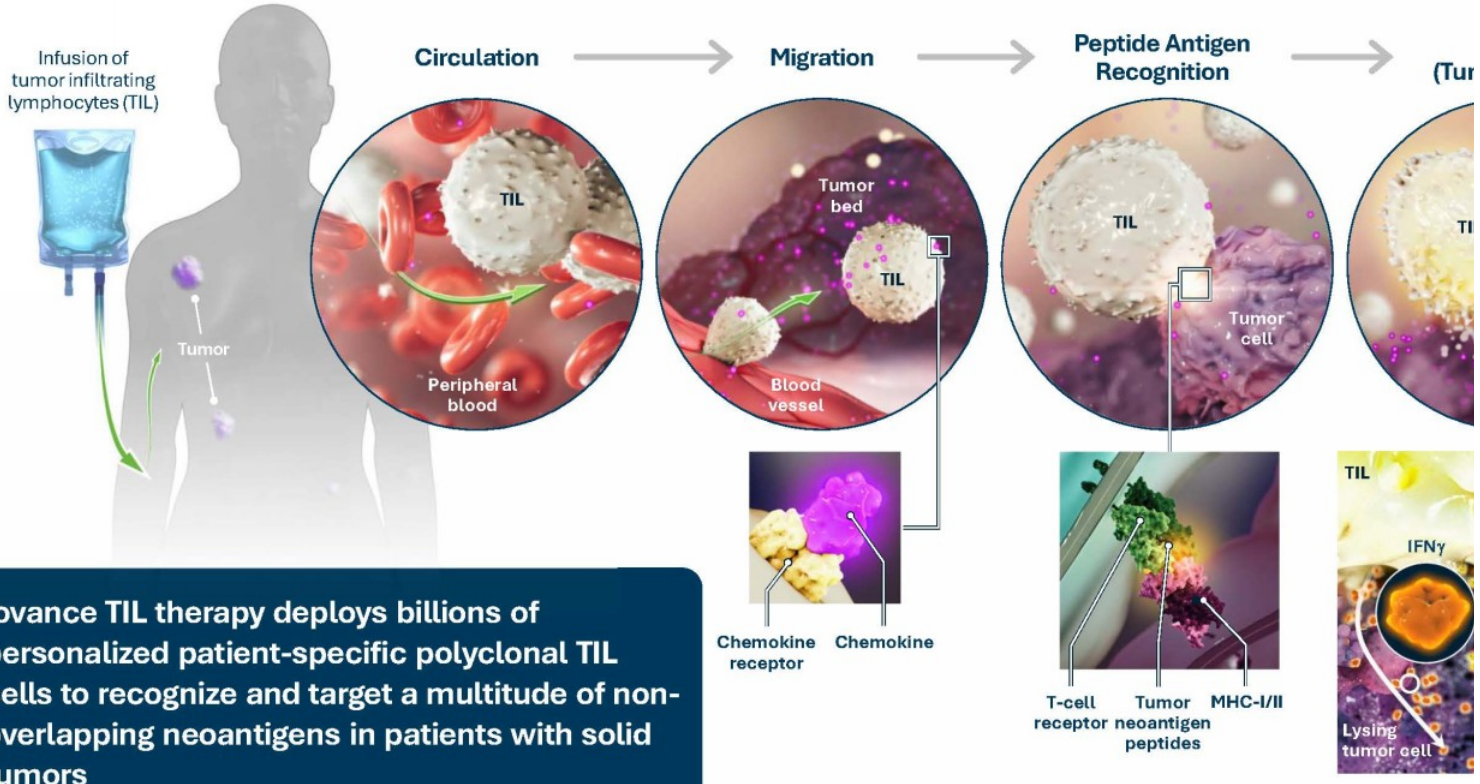
TIL – Unique Mechanism of Action

- Highly personalized
- One-time therapy
- Patient's own immune system amplified and rejuvenated



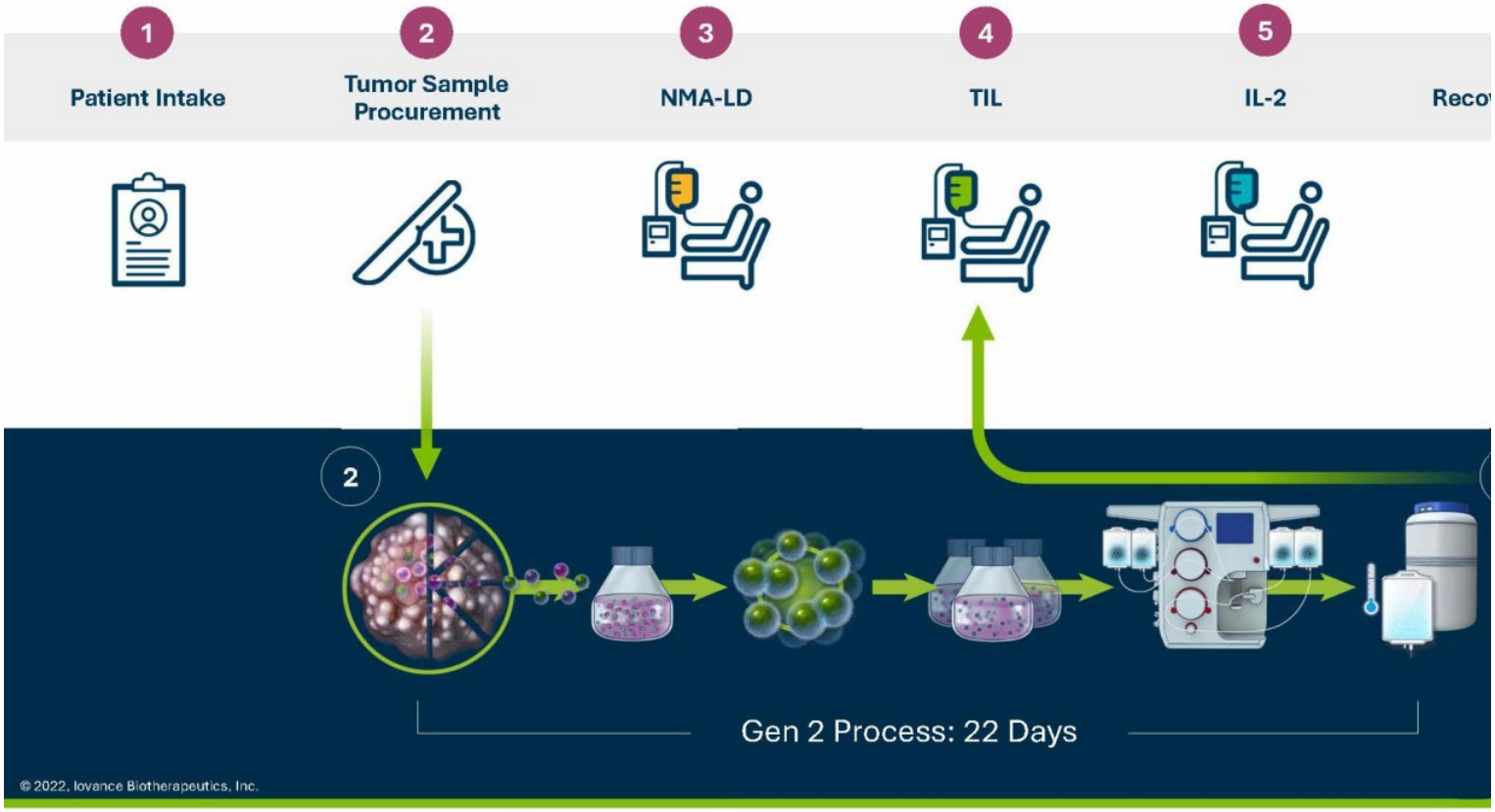
1. Simpson-Abelson et al., ESMO 2020

TIL Mechanism of Action



Iovance TIL therapy deploys billions of personalized patient-specific polyclonal TIL cells to recognize and target a multitude of non-overlapping neoantigens in patients with solid tumors

Iovance Streamlined 22-Day GMP Manufacturing Process



Iovance Cell Therapy Center: *i*CTC

Built-to-suit custom facility in Navy Yard Philadelphia

136,000 ft^2, $85M investment

LEED gold certification for core and shell building

First set of clean rooms occupied

Clinical supply initiated 3Q21

Commercial manufacturing expected with BLA approval

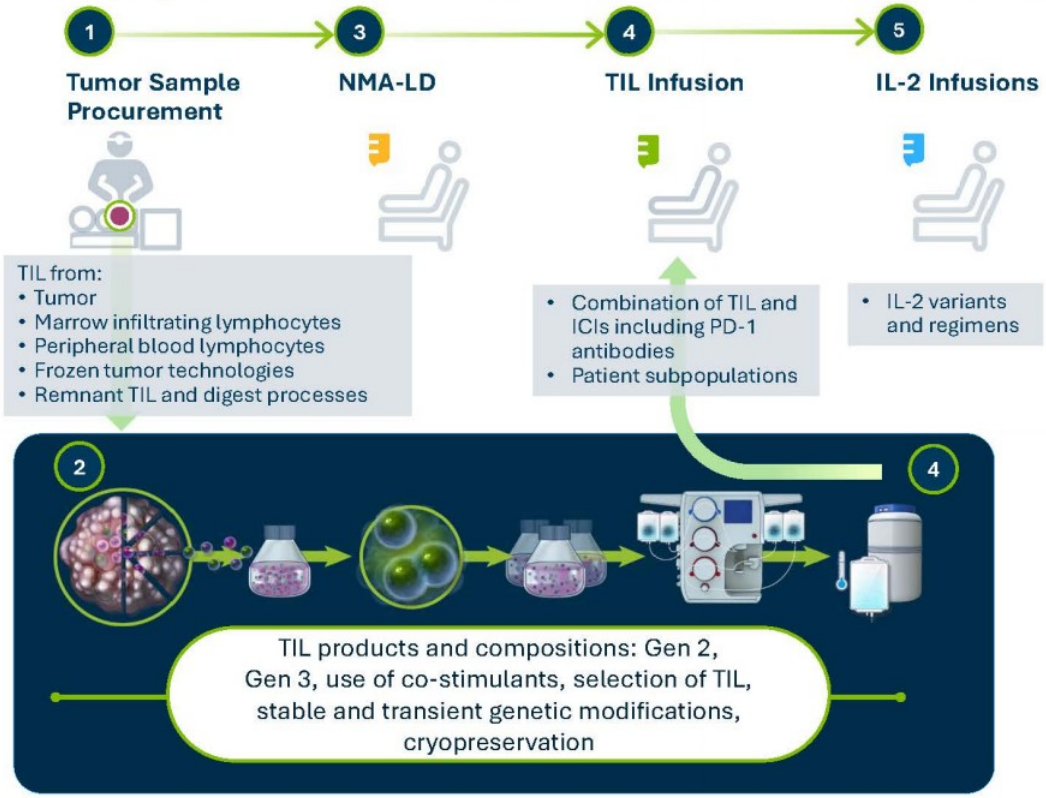
Significant reduction in COGS anticipated

Honorable Mention for 2022 ISPE Facility of the Year (FOYA) Awards

Leading Cell Therapy Manufacturing Fac

IOVANCE
BIOTHERAPEUTICS
CELL THERAPY CENTER

Broad, Iovance-Owned IP Around TIL Therapy



- ✓ >40 granted or a and internationa
- ✓ Compositions of TIL products
- ✓ Methods of treat broad range of c
- ✓ Manufacturing p

Clinical Data Highlights

Potential Market for Metastatic Melanoma

Unmet Needs to Increase Response Rates in Early Line and Post-Immune Checkpoint Inhibitors

"For patients who progress on anti-PD-1 therapy, there is an unfilled need for efficacious and durable treatment options. The latest results with lifileucel suggest that intervention with TIL therapy, upon progression, can achieve this goal for patients and should be considered as appropriate therapy."

Omid Hamid, MD
Chief of Research/Immuno-Oncology
The Angeles Clinic & Research Institute

309k New cases WW each year[1]

62k

106k Diagnoses in U.S. each year[2]

7k De ea

Available Care:

1st line: Anti-PD-1 Immunotherapy 21%-33% ORR[3]

BRAF/MEK inhibitors for BRAF positive

Limited options after progressi checkpoint and BRAF/MEK inhi

1. Global Burden of Disease Cancer Collaboration, JAMA Oncol 2019
2. https://seer.cancer.gov accessed February 2022
3. Keytruda USPI accessed Mar 2021
4. Keytruda USPI accessed Mar 2021 (4%) and Weber et al., Lancet Oncol 2015 (ICC 10%)
5. Kirchburger et al., Eur J Cancer 2016 and Goldinger et al., J Clin Oncol 2018

ASCO 2021

Iovance TIL Clinical Data Highlights in Melanoma

Single-Agent Lifileucel Following Progression on Anti-PD-1 Therapy
(C-144-01 Cohort 2, N=66)[1]

36% ORR

Median DOR not reached

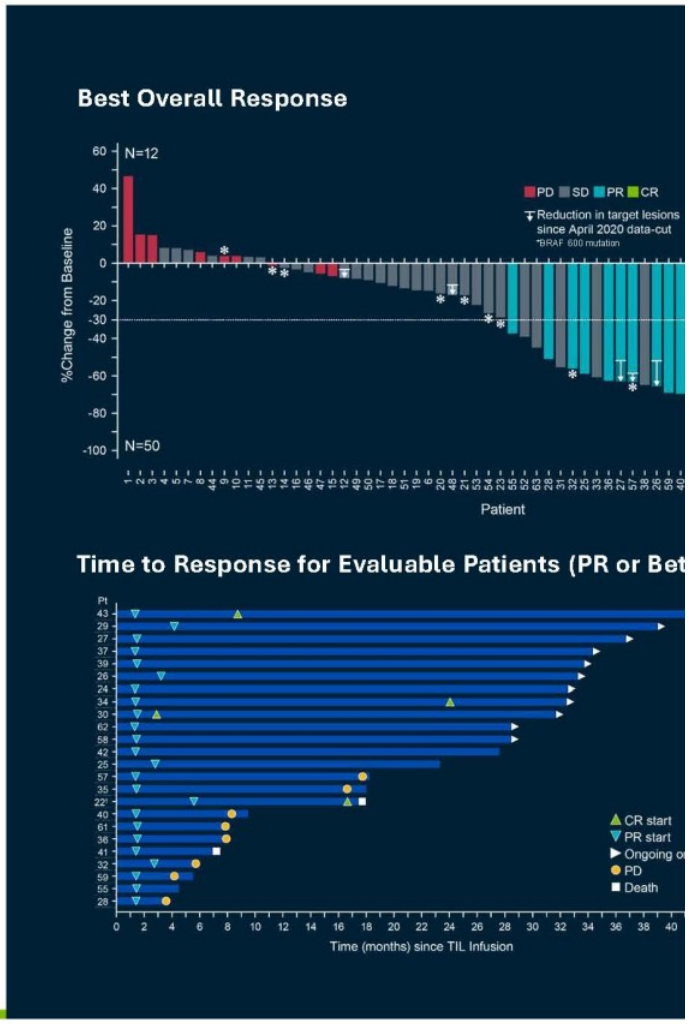
33.1 months

Median study follow up

Responses continue to deepen over time:

- 17% of patients had deepening of response
- 1 PR converted to CR 24 months post-lifileucel

1. As assessed by investigator using RECIST 1.1 (data extraction: April 22, 2021). Larkin, et. al. ASCO 2021. Abstract #9505.
Abbreviations: CR, complete response; DOR, duration of response; ORR, overall response rate; PR, partial response; SD, stable disease



Potential Market for Non-Small Cell Lung Cancer (NSCLC)

Addressing a Defined Unmet Need in Second Line NSCLC

"The clinical data for LN-145 in heavily treated patients with metastatic non-small cell lung cancer is exciting. It represents the first experience for TIL monotherapy to show clinical benefit in metastatic non-small cell lung cancer."

Adam J. Schoenfeld, MD
Medical Oncologist
Memorial Sloan Kettering Cancer Center

2.1M New cases WW each year[1]

1.8M

236k Diagnoses in U.S. each year[2]

132k

Available Care:

Checkpoint Inhibitor + Chemo as 1st line option

9-13% ORR in 2nd line NSC progression o

1. Global Burden of Disease Cancer Collaboration, JAMA Oncol 2019
2. https://seer.cancer.gov accessed February 2022
3. Brahmer et al., NEJM 2015; Borghaei et al., NEJM 2015; Herbst et al., Lancet 2016; Rittmeyer et al., Lancet

SITC 2021

Iovance TIL Clinical Data Highlights in NSCLC

Single-Agent LN-145 Following Progression on Anti-PD-1 Therapy
(IOV-COM-202 Cohort 3B, N=28)[1]

21% ORR **20.7+** months ongoing CR

Heavily Pre-Treated Patient Population

- All received prior anti-PD-1 / anti-PD-L1 therapy
- 24/28 patients (85.7%), including all responders, received ≥2 prior lines of systemic therapy

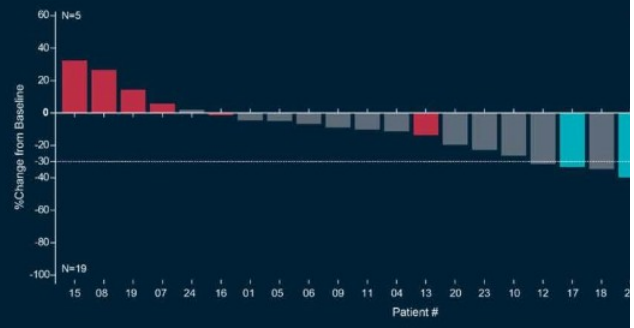
Long-term CRs Observed in Iovance (≥2 prior lines) and Moffitt[2] (post-nivo) TIL Studies in NSCLC

1. As assessed by investigator using RECIST 1.1 (August 24, 2021 data cutoff). Schoenfeld et al, SITC 2021, Abstract 458.
2. Creelan et al., Nat Med 2021
3. Responses still ongoing at time of last assessment for patients 2 and 17

*Patient 2 is reported as a CR based on negative FDG-PET scans by investigator

Abbreviations: CR, complete response; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; TIL, tumor infiltrating lymphocytes; nivo, nivolumab

Best Overall Response for Evaluable Patients[1] (n=24)



Time to Response for Confirmed Responders[1] (PR or Bette

Pt ID	# of Lines of Prior Therapy	BOR to Prior ICI	PD-L1 TPS (%)*	Driver Oncogene Mutations
2	3	PD	<1	Not assessed
17	2	PD	70	*KRAS*^{G12C}
25	3	PD	0	Not assessed
26	3	PR	40	*KRAS*^{G12D}
22	2	PR	5	None detected
28	3	SD	90	None detected

TIL for Solid Tumors in Earlier Treatment Settings

Unmet Need to Improve Rate and Depth of Responses with Manageable Long-term Safety

> Immune checkpoint inhibitors are standard-of-care in the treatment of several types of advanced cancer, including cervical cancer, melanoma, and HNSCC. Unmet needs remain to help more patients respond and to enhance the depth and durability of responses."

David M. O'Malley, MD
Professor of Obstetrics and Gynecology at The Ohio State University College of Medicine; Director of the Division of Gynecologic Oncology, The Ohio State University Comprehensive Cancer Center (OSUCCC – James)

Available Care

Front-line standard of care pembrolizumab monotherapy:

- 33% ORR (6% CR rate) in advanced melanoma[1]
- 17% ORR in HNSCC[2]

2nd line pembrolizumab in cervical cancer patients following standard of care systemic chemotherapy

- 11%-14% ORR[3]

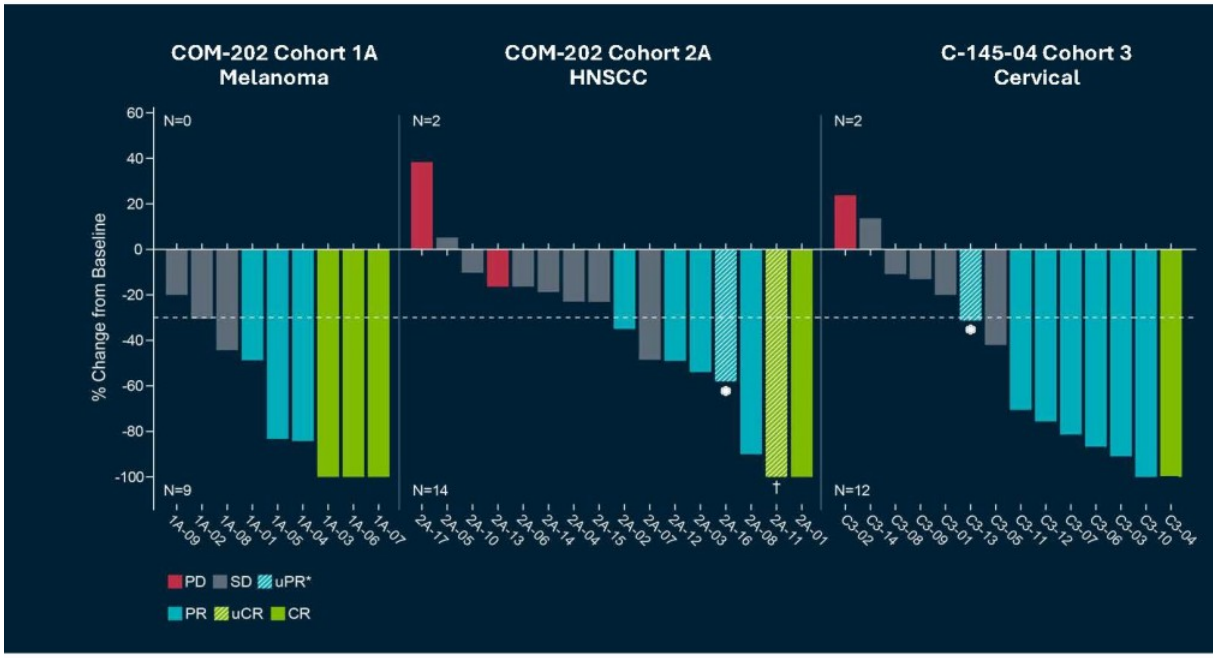
1. Robert C, et al. N Engl J Med 2015; 372:2521-2532
2. Burtness B, et al. Lancet 2019; 394:1915-1928
3. KEYTRUDA (pembrolizumab) USPI

Abbreviations: HNSCC, head and neck squamous cell carcinoma; ORR, objective response rate; TIL, tumor infiltrating lymphocytes

SITC 2021

Best Overall Response for Iovance TIL+Pembro in 3 Solid Tu

Consistent Reductions in Tumor Burden Compared to Pembro Alone in Melanoma, Cervical and HNSCC[1]



ORR

(Full Analysi

- Melanoma, (including 3
- HNSCC, 38
- Cervical, 5

Tumor burde in nearly all e evaluable pa

1. O'Malley et al, SITC 2021, Abstract 492 (Data cutoff: September 22, 2021)

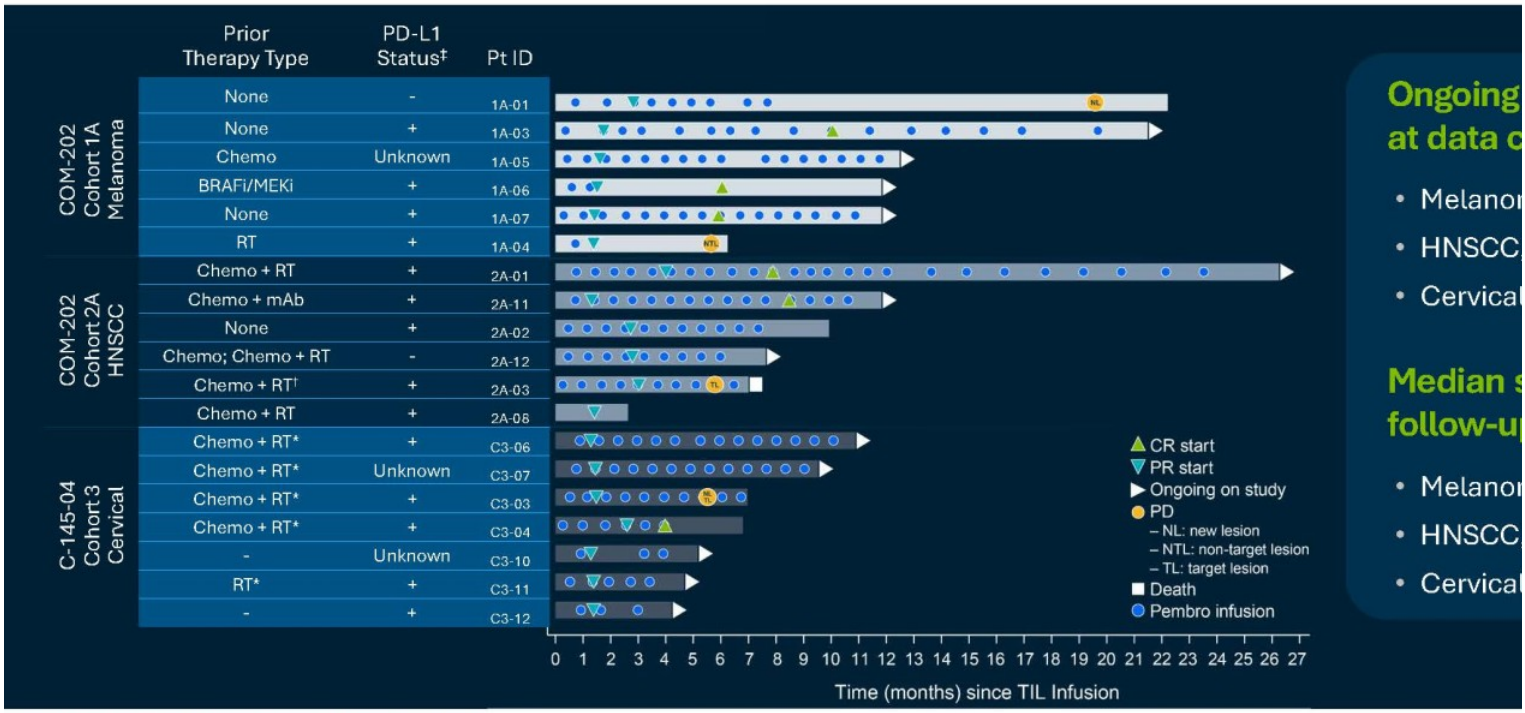
*Patients 2A-16 and C3-13 had a first PR assessment but had not reached the confirmatory assessment at the time of the data cut

†Patient 2A-11 had a first CR assessment but had not reached the confirmatory assessment at the time of the data cut but had previously achieved a PR and is included as a confirmed responder per RECIST 1.1

Abbreviations: CR, complete response; HNSCC, head and neck squamous cell carcinoma; PD, progressive disease; pembro, pembrolizumab; PR, partial response; SD, stable disease; uCR, unconfirmed complete response; uPR, unconfirmed partial response

SITC 2021

Time to Response (PR or Better) in 3 Solid Tumors[1]



1. O'Malley et al, SITC 2021, Abstract 492 (Data cutoff: September 22, 2021)

*Prior therapies given for loco-regional disease †Treatment for loco-regional disease with progression 12 months after completion of therapy ‡Positive, defined as TPS ≥5% (melanoma), CPS ≥20% (HNSCC), CPS ≥1% (cervical) §Based on overall survival data using the reverse Kaplan-Meier method

Each bar is presented for each patient starting from date of TIL infusion up to date of new anti-cancer therapy, end of assessment, death, or data cutoff date, whichever occurs earlier

Abbreviations: Chemo, chemotherapy; CPS, combined positive score; CR, complete response; PD-L1, programmed death ligand-1; pembro, pembrolizumab; PR, partial response; RT, radiotherapy; TIL, tumor infiltrating lymphocytes; TPS, tumor proportion score; NL, new lesion; NTL, non-target lesion; TL, target lesion

Best Overall Response (by Investigator) – April 2022 Update

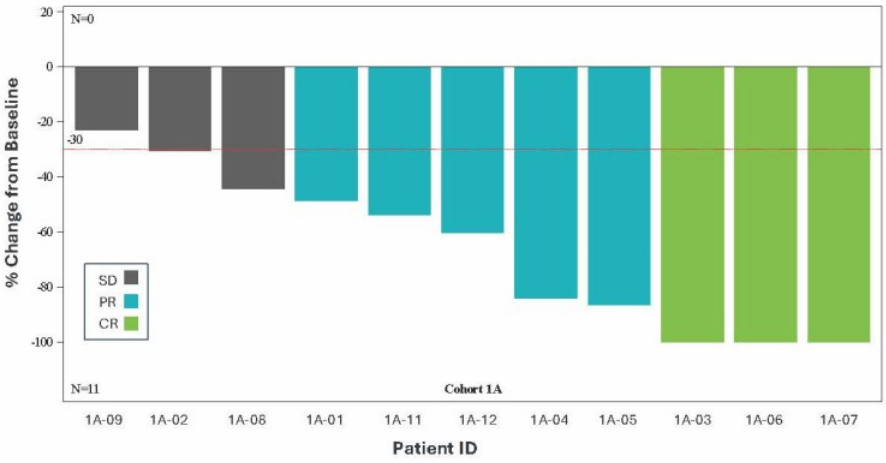
	IOV-COM-202 Cohort 1A, Melanoma (N=12)
Objective Response Rate, n (%)	**8 (66.7)**
(95% CI)	(34.9, 90.1)
Disease Control Rate, n (%)	**11 (91.7)**
(95% CI)	(61.5, 99.8)
Best Overall Response, n (%)	
CR	3 (25.0)
PR	5 (41.7)
SD	3 (25.0)
PD	0
NE	1 (8.3)

CR: complete response, PR: partial response, SD: stable disease, PD: progressive disease, NE: non-evaluable

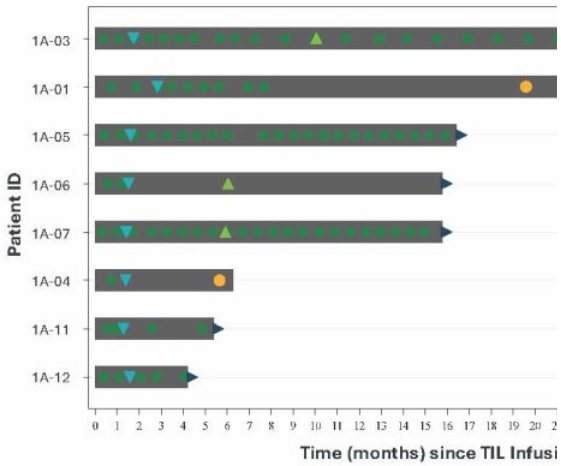
IOV-COM-202 Cohort 1A Melanoma Combination (TIL+Pembrolizumab) - Data Cutoff: January 20, 2022

Efficacy: Best Overall Response and Time to Response for Evalual Patients (by Investigator) – April 2022 Update

Best Overall Response for Evaluable Patients



Time to Response[1]

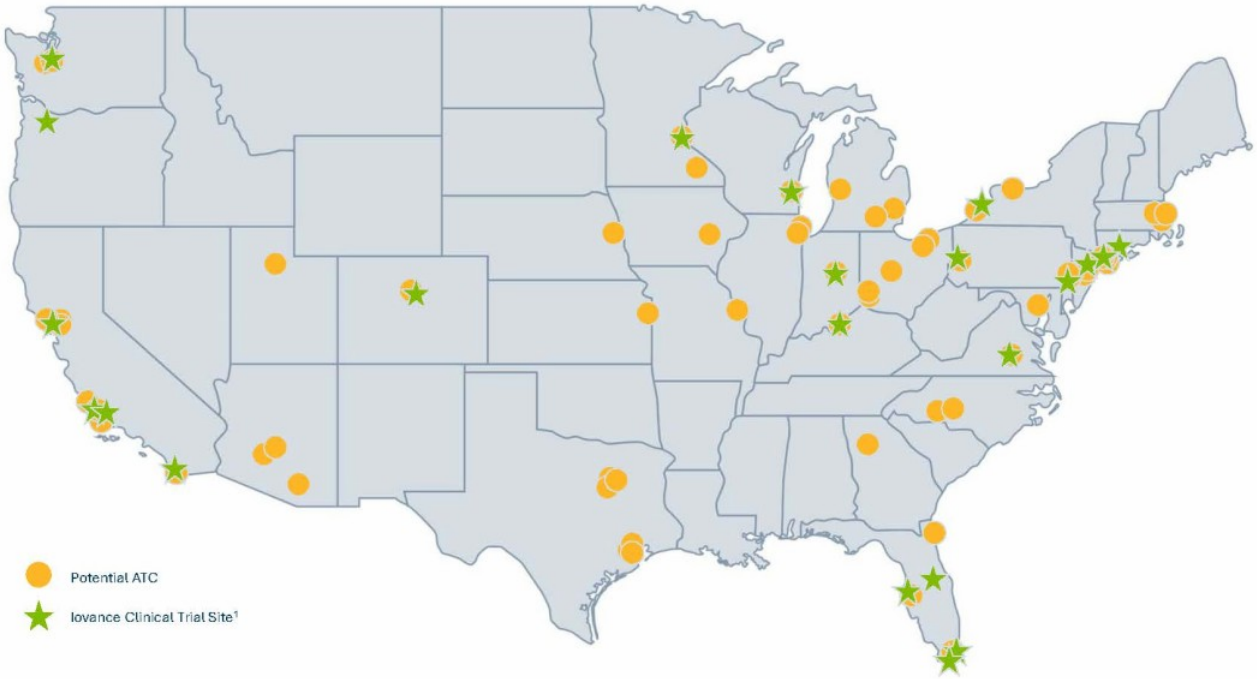


[1]Each bar is presented for each patient starting from date of TIL infusion up to date of new anti-cancer therapy, end of assessment, death, or data cutoff date, whichever occurs earlier.
CR = complete response, PR = partial response, SD = stable disease, Pembro = pembrolizumab

Launch Preparation


Best-in-Class Manufacturing
Continuous cost, quality & efficiency improvement
Increase throughput
Redundant & reliable suppliers
Reduce material costs
Consistent success rates
Reduce overhead costs
© 2022, Iovance Biotherapeutics, Inc.

Targeting Potential Authorized Treatment Centers (ATCs)



Targeting
Consider

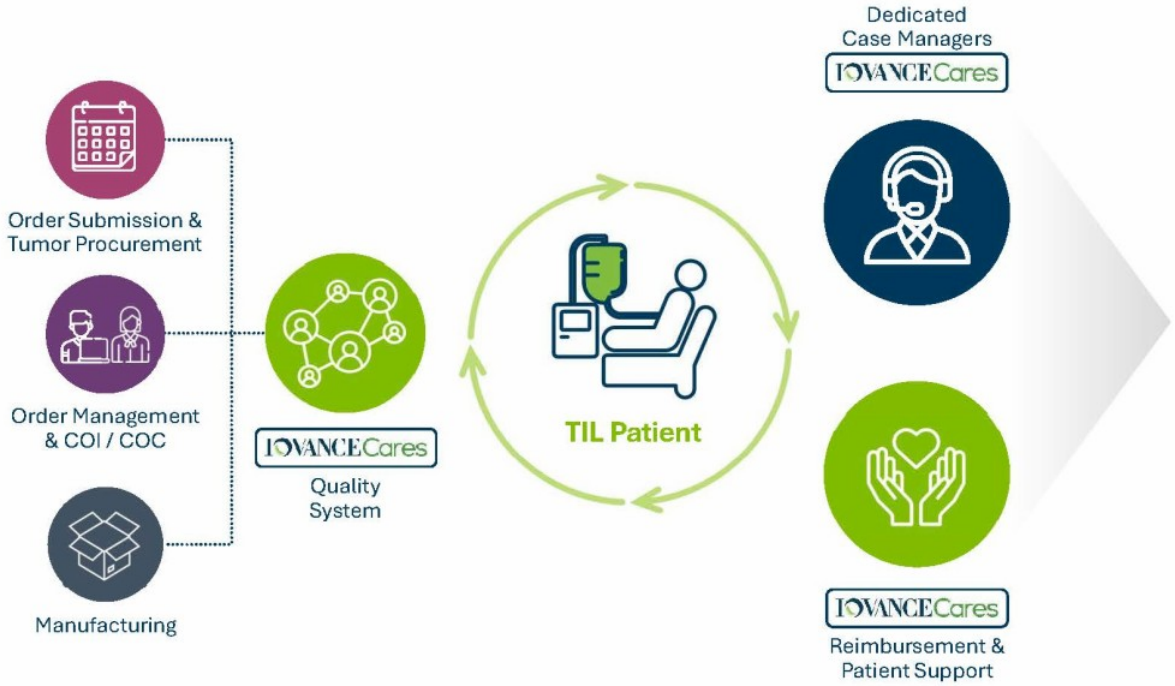
- Patient v
- NCCN st
- Existing c
- Iovance c

Drive Der

- Top acco
- Commur

1. ClinicalTrials.gov

Supporting Providers & Patients: IovanceCares™



Abbreviations: COI, Chain of Identity; COC, Chain of Custody

Research Pipeline

What's Next

Cellectis TALEN® collaboration agreement to support clinical programs[1]

IOV-4001 IND allowance

PD-1+ selected TIL

CD39/69 double negative TILs[2]

Gen 3 (16-day) process (COM-202)

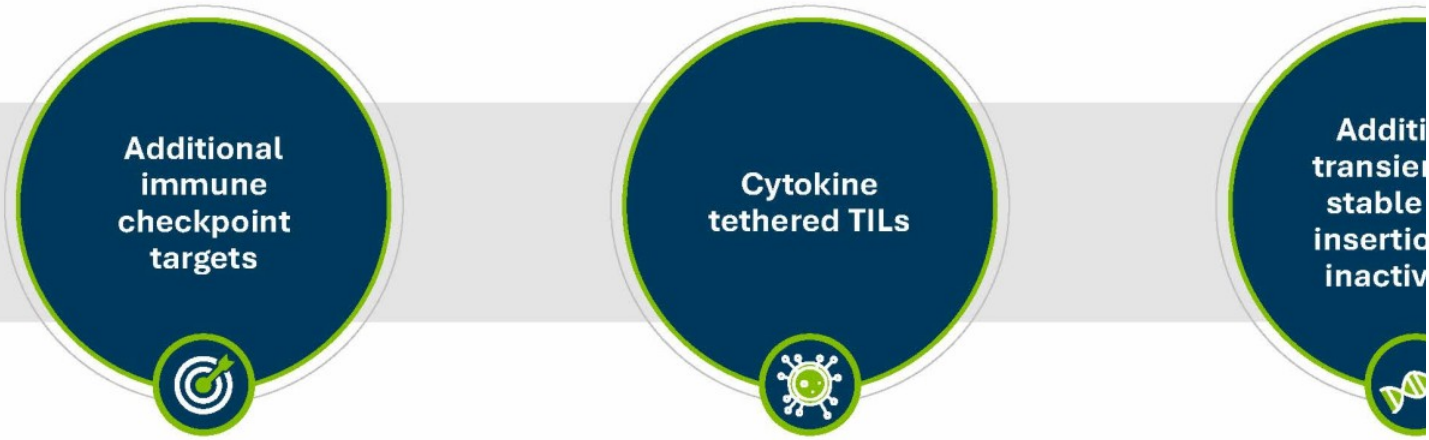
Core biopsy (LUN-202 study)

IOV-30
lice
No
enal

1. Ritthipichai et al., ESMO 2020; 2. Cubas et al., ESMO IO 2021

Advancing Genetically-Modified TIL Toward the Clinic

IND Allowance for PD-1 Inactivated TIL (IOV-4001) to Enter Clinical Study in 20



Financial Summary & Milestones

Well-Capitalized in Pursuit of TIL Commercialization

March 31, 2022	In millions (unaudite
Common shares outstanding	157.
Preferred shares outstanding	2.9
Stock options and restricted stock units outstanding	17.
Cash, cash equivalents, investments, restricted cash	$516.0
Anticipated cash runway sufficient into 2024	

1. Preferred shares are shown on an as-converted basis
2. Includes Restricted Cash of $6.1 million as of March 31, 2022


2021
Accomplishments
Anticipated
2022 Milestones
REGULATORY
BLA: FDA feedback received for potency assays; additional assay data submission & interactions 2H21
BLA: on track for August 2022 BLA submis
PIPELINE
Melanoma and Cervical: TIL + pembrolizumab data at ASCO and SITC 2021
Melanoma: Cohort 4 data
NSCLC: enroll IOV-LUN-202 study, execut FDA feedback
Cervical: last patient dosed in Cohort 2, potential to include in BLA
Cervical: execute strategy based on FDA f
NSCLC: initial LN-145 clinical data (Cohort 3B); patient dosing in IOV-LUN-202
TIL + pembrolizumab: continue ongoing c Phase III study in frontline metastatic mel
HNSCC: expanding TIL + pembrolizumab
Genetically-modified TIL: initiate clinical s
NSCLC: LN-145 clinical data at SITC 2021 (Cohort 3B)
Research pipeline: advance new TIL produ
MANUFACTURING
Melanoma and NSCLC: 16-day Gen 3 process in clinic
Continue GMP commercial readiness acti
Completion of Navy Yard GMP facility (iCTC); start clinical manufacturing at iCTC
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Investment Highlights

Pioneering a Transformational Approach to Cure Cancer

Large market opportunity & strong unmet need

- Initial focus in post-checkpoint solid tumors
- Expansion into combinations and earlier lines of therapy
- Company-sponsored trials in melanoma, cervical, head & neck, NSCLC, and chronic lymphocytic leukemia (CLL)

Potential to be first one-time cell therapy approved for solid tumors

- Accelerated path to approval in melanoma and cervical cancer
- BLA submission expected 2022
- Melanoma: RMAT, Orphan Drug, and Fast Track
- Cervical cancer: BTD, Orphan Drug, and Fast Track

Efficient & scalable proprietary manufacturing

- Iovance Cell Therapy Center (*i*CTC) in Philadelphia
- Additional capacity with contract manufacturers
- Rapid 22-day Gen 2 manufacturing with 90%+ success rate
- >500 patients treated with Iovance proprietary process

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