

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 31, 2024

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.)

825 Industrial Road, Suite 400
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.

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 31, 2024, 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, including the 2024 American Society of Clinical Oncology Annual Meeting, is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Iovance Biotherapeutics, Inc. Corporate Presentation – May 31, 2024
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: June 3, 2024

Iovance Biotherapeutics, Inc.

By: /s/ Frederick G. Vogt

Name: Frederick G. Vogt, Ph.D., J.D.

Title: Interim CEO and President, and General Counsel

IOVANCE

BIO THERAPEUTICS

Corporate Overview

May 31, 2024

ADVANCING IMMUNO-ONCOLOGY

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Forward-Looking Statements

Certain matters discussed in this presentation are “forward-looking statements” of Iovance Biotherapeutics, Inc. (hereinafter referred to as the “Company,” “we,” “it,” or “our”) within the meaning of the Private Securities Litigation Reform Act of 1995 (the “PSLRA”). Without limiting the foregoing, we may, in some cases, use terms such as “predict,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “forecast,” “guidance,” “outlook,” “may,” “could,” “might,” “will,” “should,” or “could” to convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions and are in light of management’s experience and perception of historical trends, current conditions, expected future developments, and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of future events or otherwise. Forward-looking statements are 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 actual results, levels of activity, performance, achievements, and developments to be materially different from those expressed in or implied by our forward-looking statements. Important factors that could cause actual results, developments, and business decisions to differ materially from forward-looking statements in the sections titled “Risk Factors” in our filings with the U.S. Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the risks related to our ability to successfully commercialize our products, including Amtagvi and Proleukin, for which we obtain U.S. Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”) or other regulatory authority approval; the risk that the EMA or other regulatory authorities may not approve or may delay approval for our biologics license application (BLA) for lifileucel in metastatic melanoma; the acceptance by the market of our products, including Amtagvi and Proleukin, and their potential pricing and/or reimbursement; the risk that regulatory approval (in the case of our product candidates), in the U.S. and other international markets and whether such acceptance is sufficient to support continued commercial development of our products, including Amtagvi and Proleukin, or product candidates, respectively; our ability or inability to manufacture our therapies using third party manufacturing facilities; our ability to manufacture our therapies at our own facility may adversely affect our commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be representative of our sponsored trials; the risk regarding the successful integration of the recent Proleukin acquisition; the risk that the successful development or commercialization of our products, including Amtagvi and Proleukin, may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; the risk that other market factors may adversely affect the commercial potential for Amtagvi or Proleukin; the risks related to the timing of and our ability to successfully develop, maintain FDA, EMA, or other regulatory authority approval of, or other action with respect to, our product candidates; whether clinical trial results from our pivotal studies and meetings with the FDA, EMA, or other regulatory authorities may support registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities; the risk that the planned single arm Phase 2 IOV-LUN-202 trial may not support registration; preliminary and interim clinical results, which may include efficacy and safety data from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohort enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the risk that the changing landscape of cancer patients may impact our clinical trials in this indication; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA, EMA, or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA, EMA, or other regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities (including from our prior meetings with the FDA regarding cell lung cancer clinical trials); the risk that clinical data from ongoing clinical trials of Amtagvi will not continue or be repeated in ongoing or planned clinical trials or regulatory approval or renewal of authorization; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated requirements; the effects of the COVID-19 pandemic; and other factors, including general economic conditions and regulatory developments, not within our control.

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

Commercial Products

AMTAGVI[™]
(lifileuce)^l
Suspension for IV infusion

PROLEUKIN[®]
(aldesleukin)

Commercial

100+ Amtagvi Patients Enrolled by 5/9/24

Payers responsible for

200 million+

patient lives have approved Amtagvi for at least 1 patient

50 Authorized Treatment Centers by 5/28/2024

Pipeline

2 Registrational Clinical Trials

7 Active Clinical Trials

5 Tumor Types in Clinic

3 Fast Track **1** BTD **1** RMAT Designations

People & Assets

~\$363M

Cash Position as of 3/31/24



120+

U.S. and International Patents

600+

Employees

Iovance Solid Tumor Portfolio Highlights

		INDICATIONS	PHASE 1	PHASE 2	PHAS
Commercial	 (lifileucel) ^{Suspension for IV infusion}	Post-anti-PD-1 advanced melanoma (U.S.) Planned submissions: EU (2Q24), U.K. & Canada (2H24)	[Green bar]		
	 (Aldesleukin) Recombinant IL-2	Amtagvi treatment regimen (U.S.) Advanced melanoma, renal cell carcinoma (U.S., ex-U.S.)	[Green bar]		
Label Expansion Opportunities	Registration-Directed	Lifileucel + pembrolizumab	Frontline advanced melanoma	TILVANCE-301 Phase 3 (FTD, Confirmator	
		Lifileucel	2L post-chemo & anti-PD-1 advanced NSCLC	IOV-LUN-202: Cohorts 1&2	
	Lifileucel Pipeline	Lifileucel	2L post-chemo & anti-PD-1 endometrial cancer	Planned	
		Lifileucel, Lifileucel + ICI	2-4L incl. post-anti-PD-1 advanced NSCLC	IOV-COM-202: Cohorts 3A, 3B*, 3C	
		Lifileucel + ICI	1L advanced melanoma	IOV-COM-202: Cohort 1A	
		Lifileucel core biopsy	2L post-chemo & post-anti-PD-1 advanced NSCLC	IOV-LUN-202: Cohort 3	
Next-Generation Products	PD-1 Inactivated TIL (IOV-4001)	Post anti-PD1 advanced melanoma	IOV-GM1-201: Cohort 1		
	PD-1 Inactivated TIL (IOV-4001)	2-4L incl. post-anti-PD-1 advanced NSCLC	IOV-GM1-201: Cohort 2		
	IL-2 analog (IOV-3001)	TIL Treatment Regimen (planned IND in 3Q 2024)	Planned		
	IL-12 tethered TIL (IOV-5001)	Undisclosed (planned IND early 2025)	Planned		

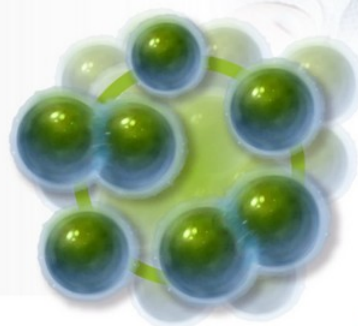
*Enrollment complete
 Abbreviations: 1L=first line; 2L=second line; 4L=fourth line; BTD=Breakthrough Therapy Designation; FTD=Fast Track Designation; ICI=immune checkpoint inhibitor; IL-2=interleukin 2; IL-12=interleukin 12; IND=investigational new drug application; NSCLC=non-small cell lung cancer; PD-1=programmed cell death protein-1; TIL=tumor infiltrating lymphocytes

Tumor Infiltrating Lymphocytes (TIL): Leading Cell Therapy Platform for Solid Tumors

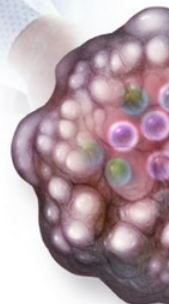
TIL – Unique Proposed Mechanism of Action

- Individualized
- One-time therapy
- Deploys the patient's own T cells to fight cancer

TIL Treatment Regimen



Patient-specific T Cells
Grown into the Billions¹

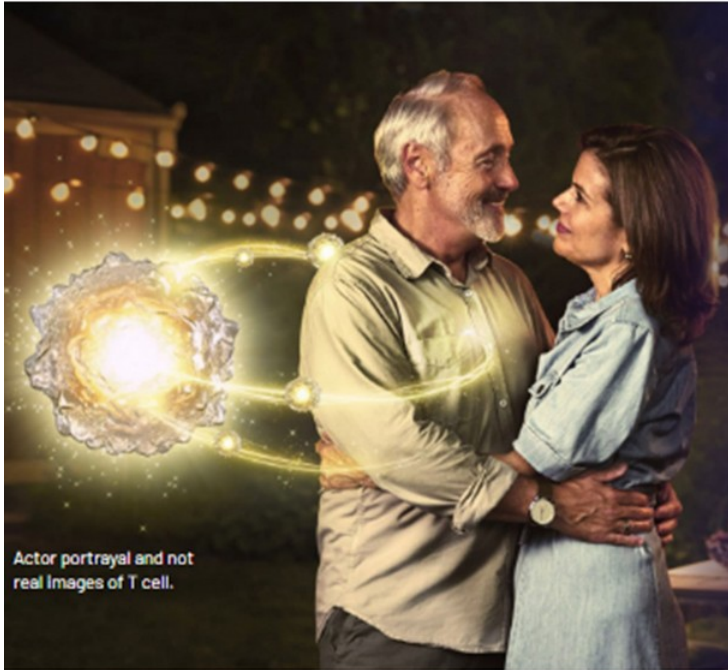


1. Amtagvi USPI



AMTAGVI[™]
(lifileucel) Suspension
for IV infusion

**First and only one-time, individualized T cell therapy
approved by FDA for a solid tumor cancer**



**Your Melanoma.
Your Cells.
Your Treatment.**

First and only FDA-approved one-time T cell therapy treatment for previously treated melanoma that has spread or cannot be treated with surgery.

[IS AMTAGVI[™] RIGHT FOR ME?](#)

[I'M READY FOR TREATMENT](#)

[HAVE OUR
CALL US](#)

Meet Toni and learn about her treatment story

Actor portrayal and not real images of T cell.

1. Amtagvi USPI

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U.S. Metastatic Melanoma Patient Population

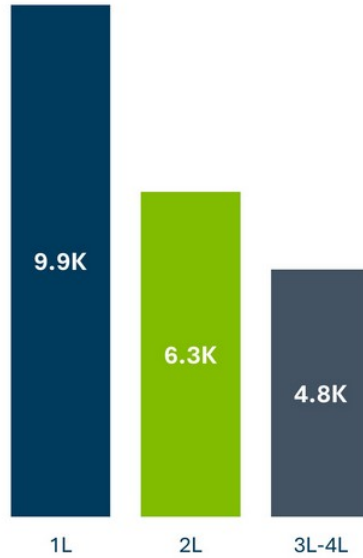
~13k

Estimated eligible advanced melanoma patients per year in U.S.¹

8k

Annual deaths in U.S.²

U.S. Melanoma Drug-Treated Population in 2021
Unresectable / Metastatic¹



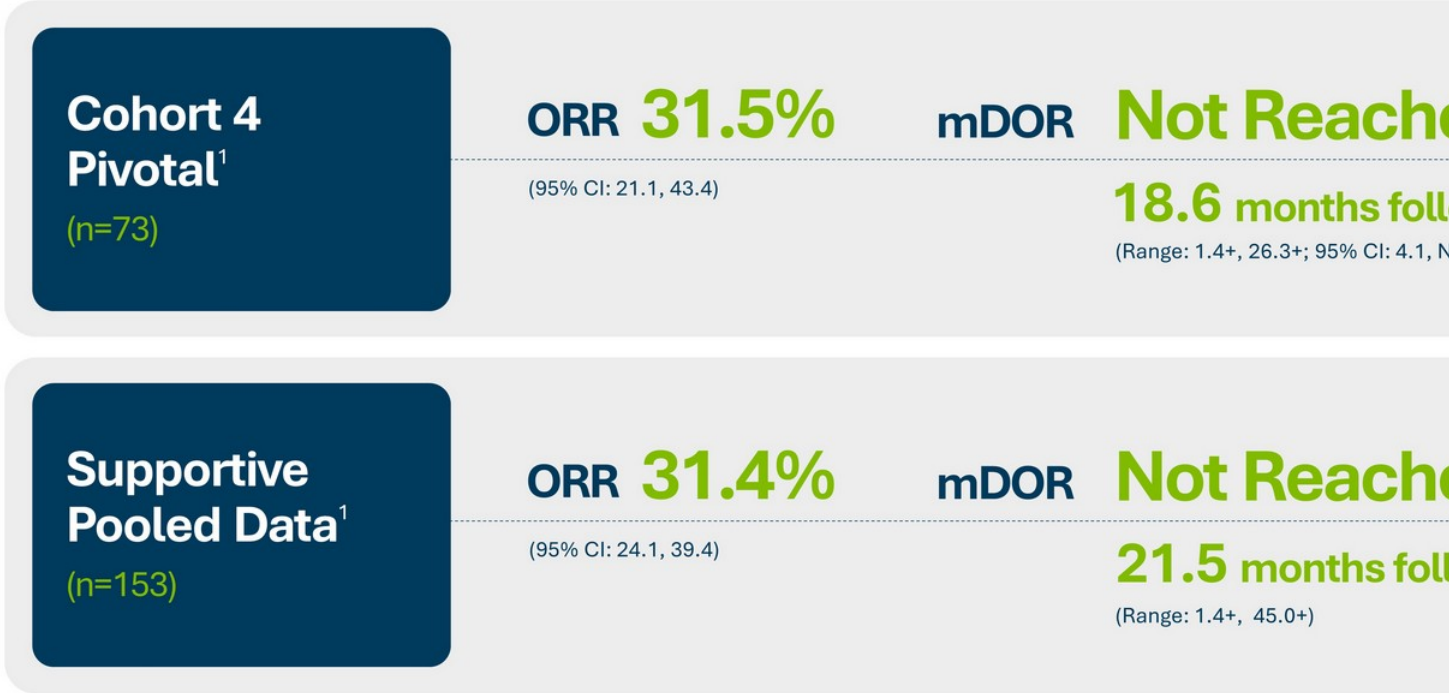
More than half progress **withi** on current regardless mutation

Amtagvi™ is preferred line or subsequent National Comprehensive Cancer Network guidelines for cutaneous r

1. Clarivate DRG Disease Landscape (2021)
2. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2024 Estimates. <https://seer.cancer.gov> accessed May 2024
3. Larkin et al, NEJM 2019; Robert et al, Lancet Oncology 2019; Tawbi et al, NEJM 2022

Abbreviations: 1L=first line therapy, 2L=second line therapy, 3L=third line therapy; 4L=fourth line therapy; ICI=immune checkpoint inhibitor

Amtagvi™ Delivered Deep and Durable Responses

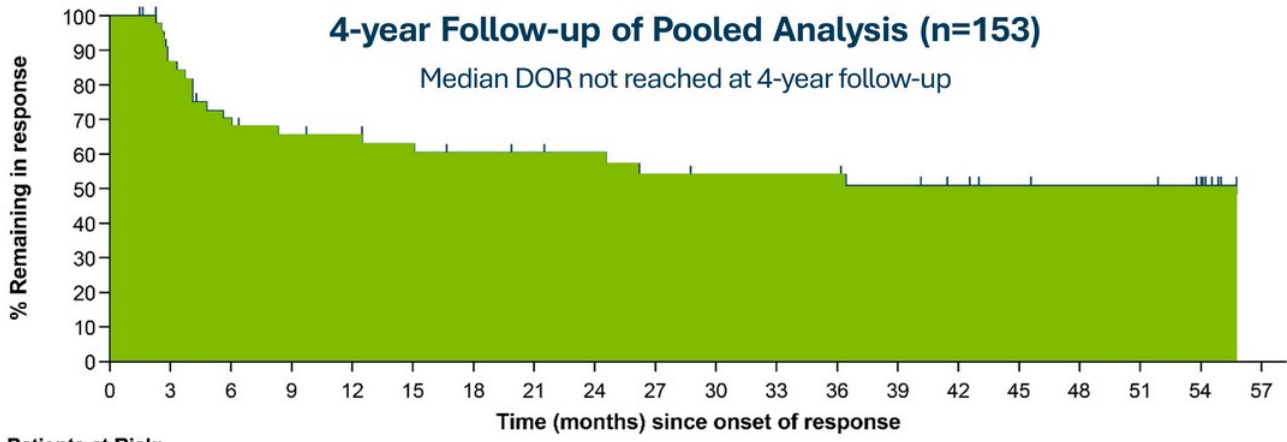


1. C-144-01 Clinical Trial, Amtagvi USPI

2. Data on file.

Abbreviations: CI=confidence interval; mDOR=median duration of response; NR=not reached; ORR=objective response rate

Amtagvi™ Durability at 4-Years



Patients at Risk:

48 38 30 27 26 24 22 21 20 18 17 17 17 15 13 11 10 10 8 0

21.9% of patients were alive at 4-year follow-up

ORR

mDOR

4

1. Medina et al, ESMO IO 2023
Abbreviations: CI=confidence interval; mDOR=median duration of response; NR=not reached; ORR=objective response rate

Amtagvi™ Patient Journey

Amtagvi Autologous T Cell Therapy



Reimbursement approval timelines between ATCs and payers for Amtagvi are decreasing over

Iovance Cell Therapy Center: iCTC

FDA-Approved Cell Therapy Manufacturing Facility
Dedicated to Commercial and Clinical TIL Cell Therapies

- Built-to-suit custom facility in Navy Yard Philadelphia
- Supplies commercial and clinical TIL therapy
- Annual capacity for up to several thousand patients as built
- Expansion underway for additional capacity within iCTC over next few years
- Control to optimize capacity, quality & COGS



IOVANCE
BIOTHERAPEUTICS
CELL THERAPY CENTER

FOYA 12
ISPE Facility of the Year Award
CATEGORY WINNER
Honorable Mention

Iovance Cell Therapy Center (iCTC): Capacity Expansion Plans

Pre-Approval
(Complete)

100s

of patients/year

Launch Prep

in core suites for
commercial

4

separate flex suites
for clinical

Today
(as built)

up to **2,000+**
patients/year¹

12

core suites for
commercial

4

separate flex suites
for clinical

Site Expansion
(in progress)²

5,000+

patients/year

24

core suites for
commercial

4

separate flex suites
for clinical

iCTC Campu
Expansion

10,000

patients/yea

iCTC bu
expansi

Automa

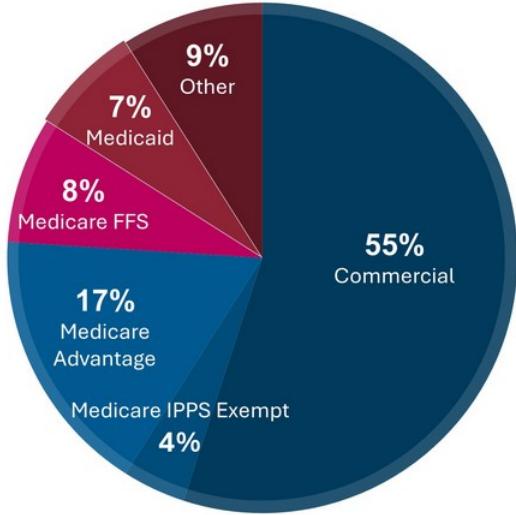
1. Ongoing staffing, CDMO provides flexibility for incremental additional capacity 2. Expansion within existing shell 3. Option to build on adjacent parcel

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Broad Market Access

Payers appreciate the significant patient need, lack of treatment options, and Amtagvi™ clinical value

Metastatic Melanoma Payer Mix¹
Amtagvi-Eligible Patients Treated in the ATC Setting



Strong Reimbursement

- Initial payer medical coverage consistent with label, clinical trial guidelines
- Strong hospital reimbursement
 - Majority of Amtagvi patients are commercially insured²
 - Inpatient payment methodology established
 - Key payers expected to reimburse provider costs

1. Metastatic Melanoma Insurance Claims Analysis, TIL-eligible patients treated in the ATC setting (1/1/2018–6/30/2021).

2. As of May 30, 2024. Data on file.

Abbreviations: ATC=Authorized Treatment Center; IPPS=Inpatient Prospective Payment System; FFS=Fee-For-Service; NCCN = National Comprehensive Cancer Network



Amtagvi™ Expansion Plans in Advanced Melanoma

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Ex-U.S.: Unmet Medical Need for Metastatic Melanoma Therapies

Expanding Amtagvi™ launch ex-U.S. to double addressable patient population

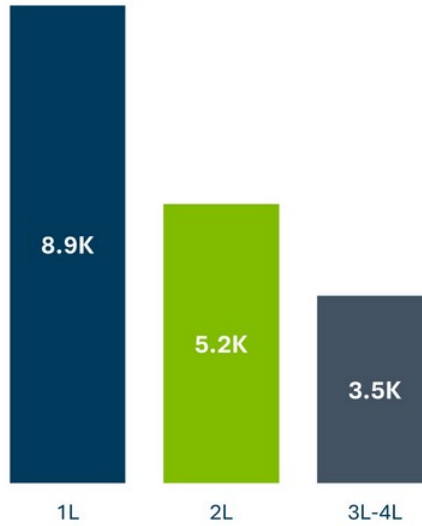
59K

Annual deaths worldwide¹

14K

Annual deaths in ex-U.S. target markets¹

EU5 Melanoma Drug-Treated Population, 2021²
Unresectable / Metastatic



Ex-U.S. Plan
2024 Submission

 **EU:** 2Q 2024

9.8K annual deaths
target EU countries

 **U.K.:** 2H 2024

2.6K annual deaths

 **Canada:** 2Q 2024

1.4K annual deaths

1. Germany, U.K., Canada, Italy, Spain, France, Netherlands, World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022

2. Clarivate DRG Disease Landscape (2021)

3. Germany, U.K., Canada, Italy, Spain, France, Netherlands, World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022

4. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022

Abbreviations: EU5=France, Germany, Italy, Spain and U.K.; 1L=first line therapy, 2L=second line therapy, 3L=third line therapy, 4L=fourth line therapy

Advanced Frontline Melanoma: ASCO Phase 2 Data Takeaway

- ICI-naïve patients with advanced melanoma treated with lifileucel plus pembrolizumab had durable responses
 - Two thirds of patients had a confirmed response by RECIST v1.1
 - Almost one third of patients had confirmed complete response
 - All evaluable patients had regression of target lesions
 - The vast majority of responses were ongoing
 - Median PFS not reached at nearly 2 years of median follow-up
 - PFS at 6 and 12 months: 64.7%
- The safety profile for one-time treatment with lifileucel combined with pembrolizumab more differentiated from the safety profiles of ICI combination regimens
- Supports TILVANCE-301, a registrational, randomized trial assessing lifileucel plus pembrolizumab in frontline advanced melanoma

Abbreviations: ICI=immune checkpoint inhibitor; PFS=progression free survival; RECIST=Response Evaluation Criteria in Solid Tumors.

Baseline Patient and Disease Characteristics

Characteristics	N=23	Characteristics
Median age, y (min, max)	51.0 (18–68)	PD-L1 TPS, n (%)
Male sex, n (%)	15 (65.2)	<1
White	23 (100)	≥1
Melanoma type, n (%)		Missing
Cutaneous	16 (69.6)	Median target lesion SOD, mm (min, max)
Acral	1 (4.3)	>3 baseline target and nontarget lesions, n (%)
Mucosal	2 (8.7)	Liver metastasis, n (%)
Unknown primary	4 (17.4)	Brain metastasis, n (%)
Metastatic staging at study entry, n (%)		LDH, n (%)
M0	2 (8.7)	<ULN
M1a	6 (26.1)	1–2 × ULN
M1b–M1d	14 (60.9)	>2 × ULN
Unknown	1 (4.3)	<i>BRAF</i> V600 mutated, n (%)
Baseline ECOG status		Prior <i>BRAF</i> /MEK inhibitor treatment
0	17 (73.9)	Median number of prior therapies (min, max) ^a
1	6 (26.1)	

Data cut

^a3 patients received prior chemotherapy, 2 patients received prior adjuvant immune checkpoint inhibitor >12 months prior to enrollment not counted as line of prior therapy per protocol. ECOG, Eastern Cooperative Oncology Group; LDH, lactate dehydrogenase; PD-L1, programmed death-ligand 1; SOD, sum of diameters; TPS, tumor proportion score; ULN, upper limit of normal.

Safety

Nonhematologic TEAEs in ≥30% of Patients^a

Preferred Terms, n (%)	N=23	
	Any grade	Grade 3/4
Chills	19 (82.6)	3 (13.0)
Pyrexia	18 (78.3)	4 (17.4)
Nausea	18 (78.3)	0
Vomiting	15 (65.2)	0
Fatigue	14 (60.9)	1 (4.3)
Febrile neutropenia	11 (47.8)	10 (43.5)
Headache	11 (47.8)	0
Diarrhea	10 (43.5)	1 (4.3)
Cough	10 (43.5)	0
Dyspnea	9 (39.1)	1 (4.3)
Alopecia	9 (39.1)	0
Decreased appetite	9 (39.1)	0
Hypertension	8 (34.8)	5 (21.7)
Rash maculopapular	8 (34.8)	3 (13.0)
Peripheral edema	8 (34.8)	1 (4.3)
Hypokalemia	8 (34.8)	0
Abdominal pain	7 (30.4)	0

^aTEAEs refer to adverse events that occur from the first dose of pembrolizumab or lifileucel infusion (whichever occurs first) up to 30 days after last dose of pembrolizumab or lifileucel infusion (whichever occurs later) or up to the start of a new anticancer therapy.

^bGrade 3/4 hematologic laboratory toxicity during the period from the start of NMA-LD to 30 days after the TIL infusion (to any resolution date). One patient had a grade 5 TEAE of sepsis.

AE, adverse event; IL-2, interleukin-2; NMA-LD, nonmyeloablative lymphodepletion; TEAE, treatment-emergent adverse event.

Grade 3/4 Hematologic Lab Abnorm

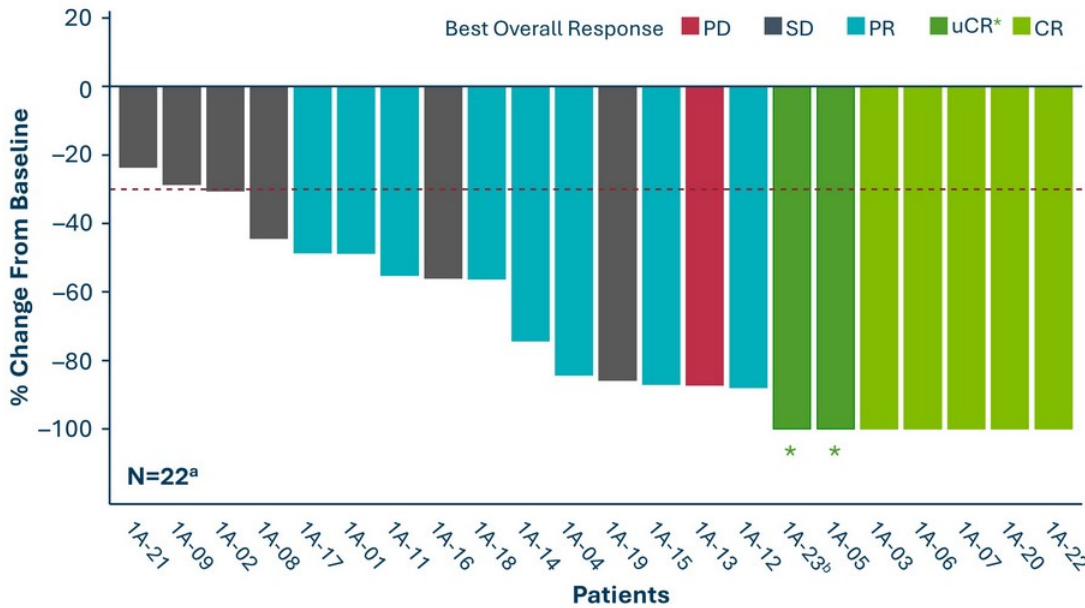
Preferred Terms, n (%)	N=
	Grade
Neutropenia	23 (100.0)
Lymphopenia	23 (100.0)
Leukopenia	22 (95.7)
Thrombocytopenia	22 (95.7)
Anemia	10 (43.5)

- By Day 30, Grade 3/4 hematologic lab abnormalities:
 - Neutropenia: 91.3%
 - Lymphopenia: 78.3%
 - Leukopenia: 95.5%
 - Thrombocytopenia: 95.5%
 - Anemia: 90.0%
- No unexpected AEs
- AEs consistent with the lifileucel regimen occurred
- AEs occurring later than 30 days after lifileucel infusion consistent with pembrolizumab monotherapy
- Safety was consistent with the underlying known safety profiles of pembrolizumab, IL-2, and IL-2**

Efficacy

ORR was 65.2%; CR rate was 30.4%

Best Percentage Change From Baseline in Target Lesion SOD



Investigator-Assessed (RECIST v1.1)

ORR, n (%)
(95% CI)
CR
PR
SD
PD
NE

All response-evaluable target lesions demonstrated regression

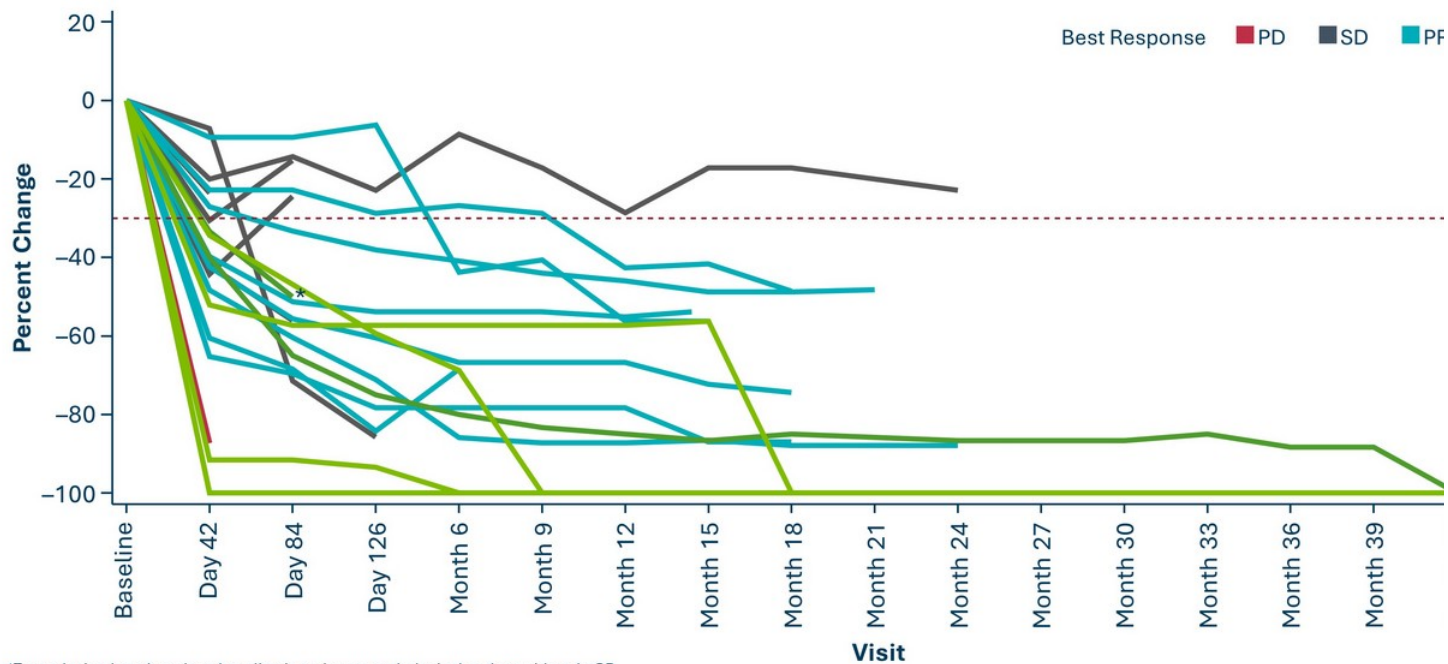
* The two uCRs have been confirmed post-dose

^aOne patient without a postdose tumor response assessment was not included. ^bTarget lesion lymph node at baseline decreased by 50% is no longer pathological, and thus is shown here as -100% representing uCR. CI, confidence interval; CR, complete response; NE, not evaluated; ORR, objective response rate; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SOD, sum of diameters; uCR, unconfirmed complete response.

Efficacy

Lifileucel + pembrolizumab demonstrated durable and deepening responses

Percent Change From Baseline in Target Lesion SOD



*Target lesion lymph node at baseline is no longer pathological and considered uCR.

†The overlapping lines at -100% represent 5 patients.

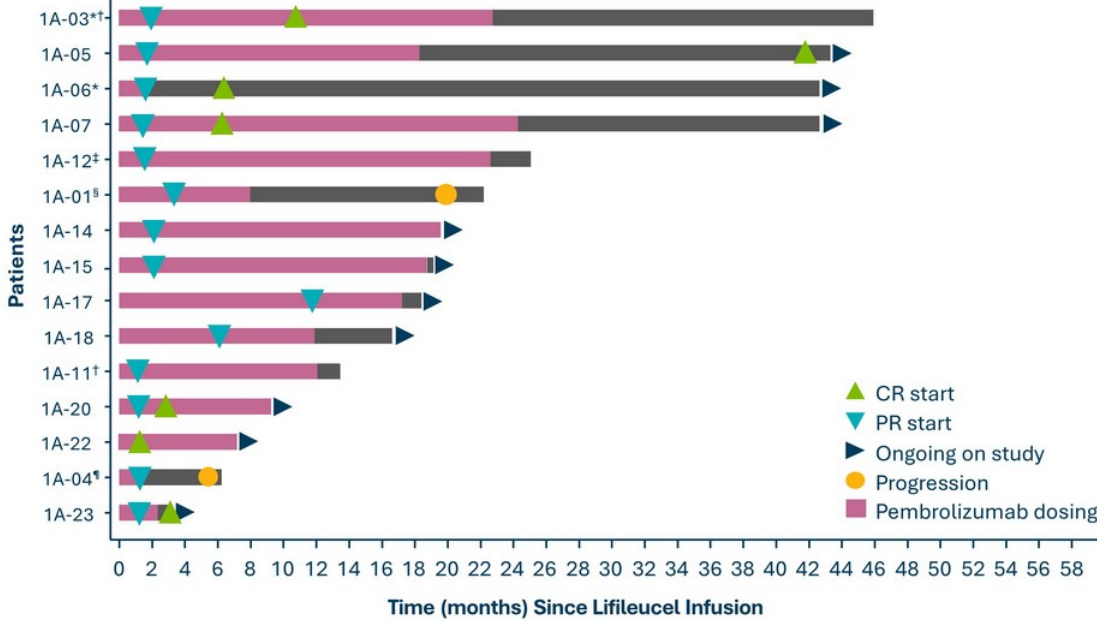
‡The two uCRs have been confirmed post-data cut.

CR, complete response; PD, progressive disease; PR, partial response; SD, stable disease; SOD, sum of diameters; uCR, unconfirmed complete response.

Efficacy

Lifileucel + pembrolizumab demonstrated durable and deepening responses

Time to Response and Time of Efficacy Assessment for Confirmed Responders (PR or Better)



Duration of Response

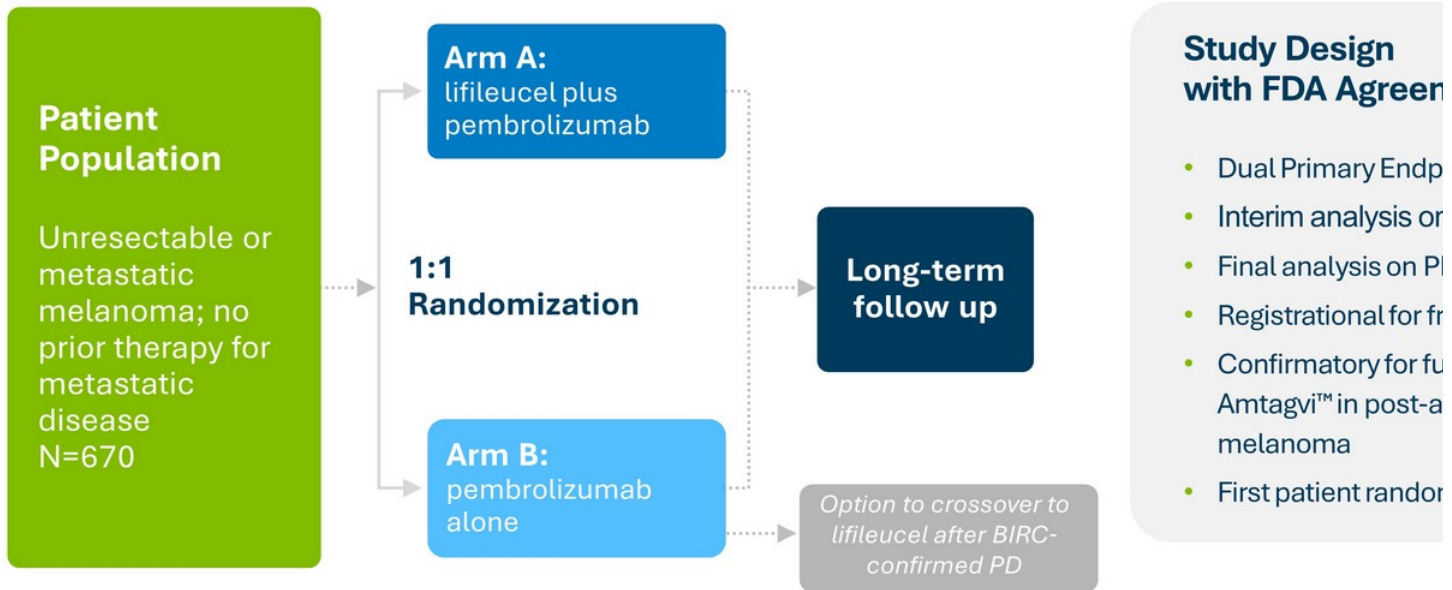
Parameter	Value
mDOR, months (95% CI)	Not Reached
DOR, n (%)	≥6 months
	≥12 months

- Median follow-up was 21 months
- **mDOR was NR**
- Median time to initial response was 1.5 months
- 10 of 15 responders (66.7%) had ongoing responses at 21 months; 20% of responders had additional responses during follow-up while in response

*CR start based on PET/CT showing no FDG uptake in all lesions and subsequently confirmed per RECIST 1.1. †Patient withdrew consent during assessment phase while still in response. ‡Discontinued from response to continue pembrolizumab off-study. §Discontinued due to disease progression of new lesion. ¶Discontinued due to disease progression of non-target lesion. CI, confidence interval; CR, complete response; DOR, duration of response; mDOR, median duration of response; (FDG) fluorodeoxyglucose; NR, not reached; PR, partial response.

TILVANCE-301 Global Phase 3 and Confirmatory Trial

Randomized, multicenter study with optional crossover to lifileucel (NCT05727904)



Abbreviations: BIRC=blinded independent review committee; ORR=objective response rate; PD=progressive disease; PD-1=programmed cell death protein-1; PFS=progression free survival

TIL Therapy Pipeline

■ Significant Market Potential in Solid Tumors and our Key Pr

91%

of all cancer cases
are solid tumors¹

1.8M

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

Expand into other indications
↓

Melanoma

U.S. Deaths¹

8K

Lung & Bronchus

125K

Endometrial

13K

Glob

1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2024 Estimates. <https://seer.cancer.gov> (accessed May 2024)
2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022

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

Addressing a Substantial Unmet Need in Metastatic NSCLC

lovance TIL clinical program:

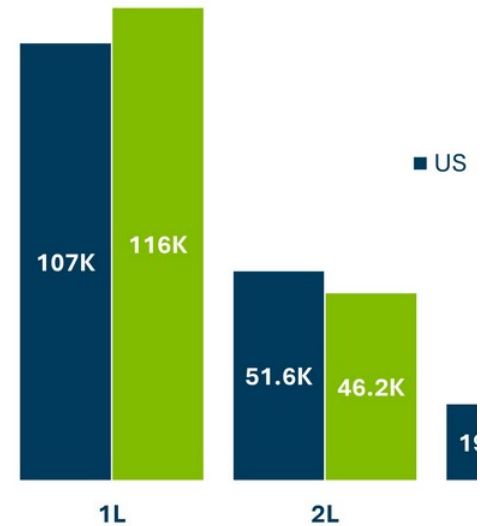
- 6 cohorts across 3 trials
- Multiple treatment regimens
- Various populations and stages of disease

125K annual deaths in U.S.¹

Leading cause of U.S. cancer deaths, accounting for ~1 in 5 cancer-related deaths²

9% 5-year survival rate² and real-world overall survival <6 months³ in U.S.

NSCLC Drug-Treated Population Stage IV (U.S. and E



1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2024 Estimates. <https://seer.cancer.gov> (accessed May 2024)

2. American Cancer Society, Lung Cancer. <https://www.cancer.org/cancer/types/lung-cancer/about.html> (accessed May 2024)

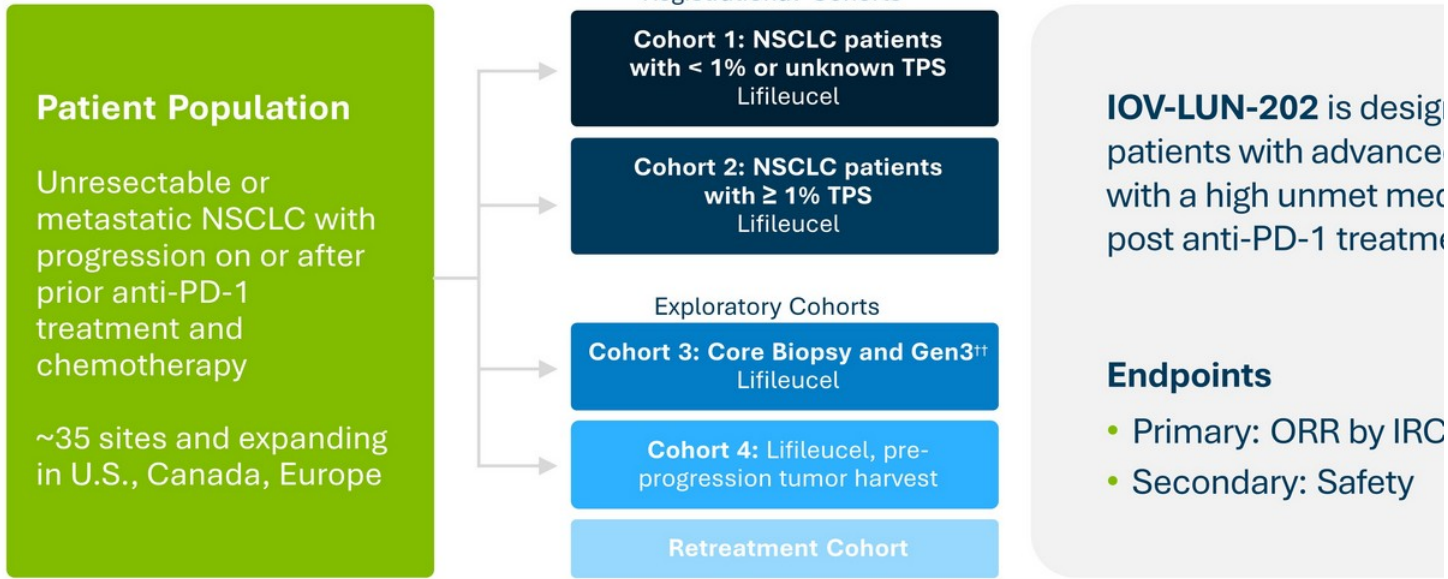
3. National Cancer Database, NSCLC survival from >1 million patients assessed. Lou Y et al. Survival trends among non-small cell lung cancer patients over a decade: impact of initial therapy at academic centers. Cancer Med. 2018.

4. Clarivate DRG Disease Landscape (2021)

Abbreviations: EU5=France, Germany, Italy, Spain and U.K.; 1L=first line therapy; 2L=second line therapy; 3L=third line therapy; NSCLC=non-small cell lung cancer

IOV-LUN-202 Registrational Trial Design

Phase 2 Multicenter Study of Lifileucel[†] in Patients Post-Anti-PD-1 NSCLC (NCT04614103)

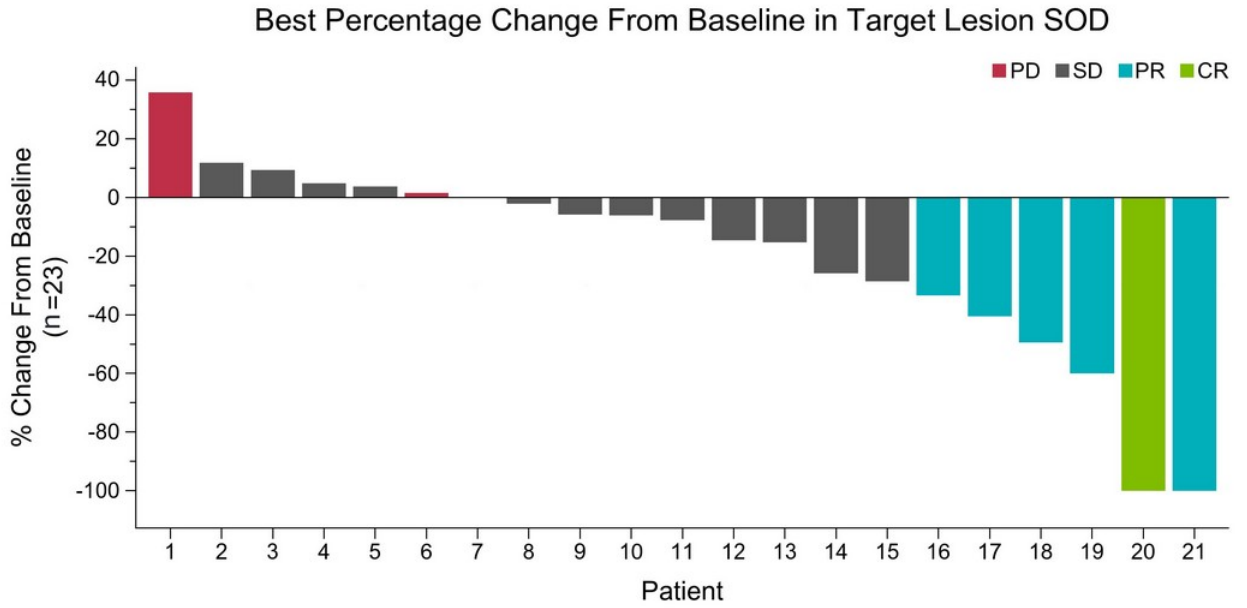


[†]Gen 2 TIL product ^{††} Cohort 3 patients unable to undergo surgical harvest, TIL grown from core biopsy

Abbreviations: Anti-PD-1=anti-programmed cell death inhibitor; IRC=independent review committee; NSCLC=non-small cell lung cancer; ORR=objective response rate; TPS=tumor proportion score

Preliminary Clinical Results for IOV-LUN-202 Cohorts 1 and 2

Objective Response Rate of 26.1% by RECIST 1.1, Regardless of PD-L1 Status



Data cut: July 6, 2023. 21 evaluable patients for response.

Abbreviations: CR, complete response; NSCLC, non-small cell lung cancer; PR, partial response; SD=stable disease; SOD, sum of diameters; TPS, tumor proportion score.

Preliminary Clinical Results for IOV-LUN-202 Cohorts 1 and 2

All Patients Progressed on or After Anti-PD-1 Therapy and Chemotherapy

	Cohort 1 + 2 (n=23) ²
Objective Response Rate, n (%)¹	6 (26.1)
(95% CI)	(10.2, 48.4)
Best overall response, n (%)	
CR	1 (4.3)
PR	5 (21.7)
SD	13 (56.5)
PD	2 (8.7)
NE	2 (8.7)

TEAEs were consistent with the underlying disease and known AE profiles of NMA-LD and IL-2

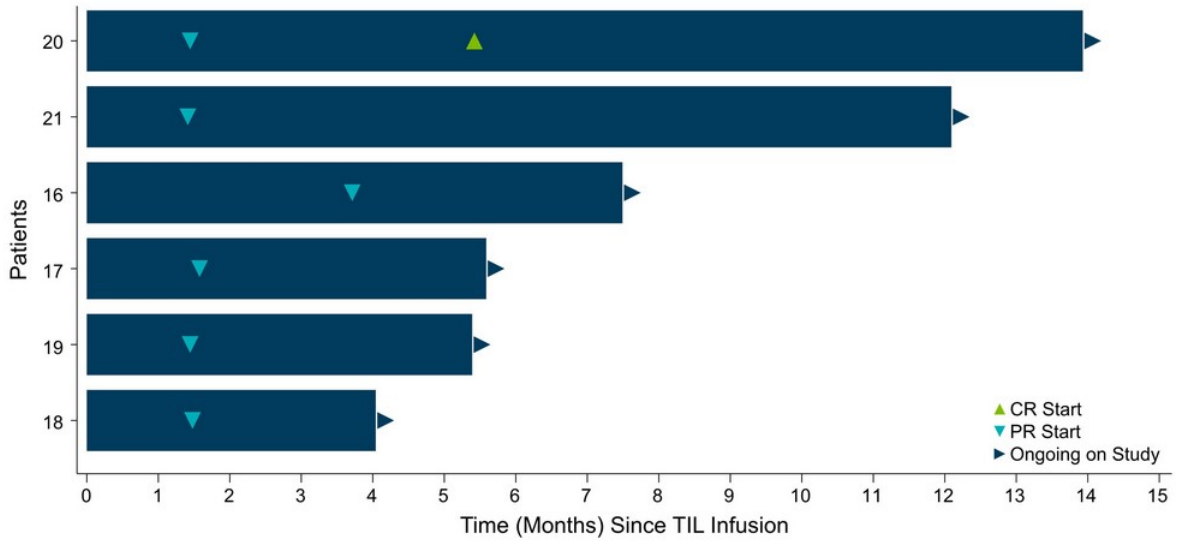
1. Data cut: July 6, 2023. Responses were assessed by investigator.

2. Patients who have progressed on or after chemotherapy and anti-PD-1 therapy for advanced (unresectable or metastatic) NSCLC without EGFR, ROS or ALK genomic mutations and had received at least one line of an FDA-approved targeted therapy if indicated by other actionable tumor mutations.

Abbreviations: AE, adverse event; CI, confidence interval; CR, complete response; ICI, immune checkpoint inhibitor; NE, not evaluable; NMA-LD, non-myeloablative lymphodepletion; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease; TEAE, treatment-emergent AE.

Preliminary Clinical Results for IOV-LUN-202 Cohorts 1 and 2

All Responses Remain Ongoing at Time of Data Cut



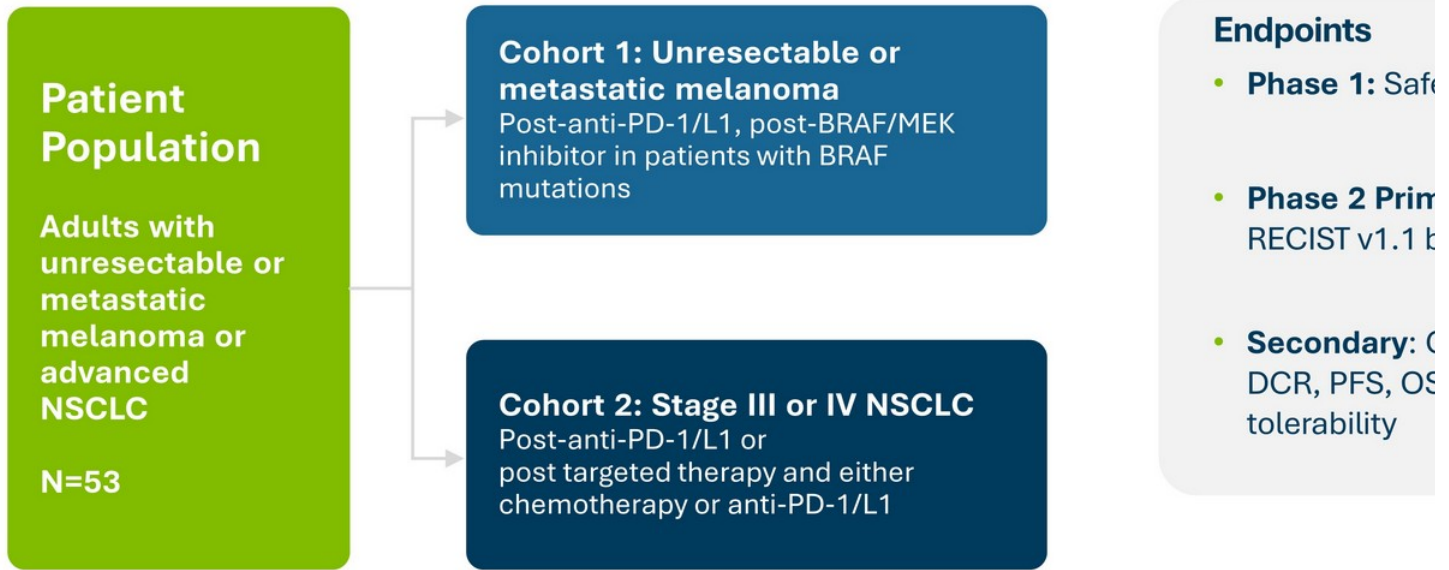
Data cut: July 6, 2023.

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

Abbreviations: CR, complete response; DOR, duration of response; NSCLC, non-small cell lung cancer; PR, partial response.

Phase 1/2 Open-Label First-in-Human Study: IOV-GM1-201

Genetically Modified, PD-1 Inactivated TIL Therapy IOV-4001 in Previously Treated Metastatic Melanoma and Advanced NSCLC (NCT05361174)



Abbreviations: Anti-PD-1=anti-programmed cell death inhibitor; CR=complete response;; DCR=disease control rate; DOR=duration of response; NSCLC=non-small cell lung cancer; ORR=objective response rate; OS=overall survival; PFS= progression free survival

Changing Treatment Landscape for Endometrial Cancer, an Immunosenescent Tumor Type

Unmet Need after Progression on/after Standard of Care (SoC) Chemotherapy and ICI

13.3K annual deaths from Uterine Cancer in U.S.¹

>90% of Uterine Cancers are Endometrial Cancers

Uterine cancer is the most common gynecologic cancer and the fourth most frequent cancer in women in the U.S.¹

67.8K

estimated new cases in U.S.¹

18.9%

5-yr survival of women with distant metastases¹

Anti-PD-(L)1 moving into front-line therapy se

- 1L chemotherapy plus anti-PD-(L)1 now consid SoC for both dMMR and pMMR tumors²
- After frontline chemotherapy (no ICI):
 - **dMMR tumors:** anti-PD-(L)1 monotherapy
 - **pMMR tumors:** Lenvatinib/pembrolizumab
- No SoC for 2L+ post-anti-PD-1
 - Molecularly defined subgroups with available targeted therapies are small
 - ORR with mono-chemotherapy after front-line chemo doublet: ~15%^{4,5}
 - Currently no data on treatments after anti-PD-(L)1

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1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2024 Estimates. <https://seer.cancer.gov> (accessed May 2024); 2. NCCN Guidelines Version 2.2024 Endometrial Carcinoma; 3. Kang et al. Nature Portfolio, Scientific Reports, 2022; 4. Makker V, et al. N Engl J Med. 2022; 5. McMeekin S, et al. Gynecol Oncol. 2015.
Abbreviations: Anti-PD-1=anti-programmed cell death inhibitor; pMMR = proficient DNA mismatch repair; dMMR = deficient DNA mismatch repair; TMB-H = tumor mutational burden high; ORR = objective response rate

Phase 2 Proof of Concept Study

Proof-of-Concept Trial in Patients with Mismatch Repair Proficient (pMMR) and Deficient (dMMR) Tumors

Endometrial Cancer Patient Population*

Recurrent, metastatic or primary unresectable disease after chemo and anti-PD-1 therapy

≤ 3 lines of prior systemic therapy with no more than 1 line of chemotherapy.

pMMR Subgroup

dMMR Subgroup

Endpoints

- **Primary:** ORR per RECIST investigator
- **Secondary:** CR rate, DCR, OS, safety and tolerability
- **Interim data, including analyses, planned in the future**

*Sample size and study population of registrational ph2 study will be determined after PoC final analysis

Abbreviations: Anti-PD-1, anti-programmed cell death inhibitor; CR, complete response; dMMR, mismatch repair deficient; pMMR, mismatch repair proficient; DCR, disease control rate; DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression free survival

Trailblazing Next-Generation TIL Programs



Genetically modify TIL

Collectis gene-editing TALEN® collaboration^{1,2}

PD-1 and other immune checkpoint targets (single and multiple knockouts)

IL-12 and other cytokine-tethered TILs



Optimize TIL composition

PD-1+ selected TIL
CD39/69 double negative TILs³



Next-generation processes

Gen 3 (16-day) process
Core biopsy

Exp nev

IO
ana
from
plan



Corporate Summary & Milestones

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Well-Capitalized in Pursuit of TIL Commercialization

March 31, 2024

(in millions)

Cash, cash equivalents, investments, restricted cash	\$362.6
Common shares outstanding	279.8
Preferred shares outstanding	2.9¹
Stock options and restricted stock units outstanding	30.8

Cash runway is sufficient well into second half of 2025²

1. Preferred shares are shown on an as-converted basis
2. Includes anticipated revenue from Amtagvi™ and Proteukin®

Anticipated 2024 Milestones

REGULATORY

- Obtain FDA approval for lifileucel in advanced melanoma (approved on Feb. 16, 2024)
- Submit EMA regulatory dossier (1H24)
- Submit additional ex-U.S. dossiers (2H24)
- Meet with FDA to discuss NSCLC registrational path/frontline study

PIPELINE

- Report clinical and pre-clinical data
- Resume enrollment in IOV-LUN-202
- Initiate Phase 2 trial in endometrial cancer
- Continue to enroll patients in clinical trials for advanced melanoma, NSCLC and gynecological cancers
- Advance new products toward clinic, including additional genetically-modified TIL therapies

MANUFACTURING

- Fulfill patient demand for commercial launch and clinical trials
- Further expand capacity to meet U.S. and ex-U.S. demand

COMMERCIAL

- Execute commercial launch (1Q24)
- On-board 50 ATCs within 90 days of PDUFA date
- On-board 70 ATCs by end of 2024

Abbreviations: ATC=Authorized Treatment Centers; EMA=European Medicines Agency; FDA=U.S. Food and Drug Association; NSCLC=non-small cell lung cancer; PDUFA=Prescription Drug User Fee Act

Corporate Highlights

Pioneering a Transformational Approach to Cure Cancer

Large Market Opportunity in High Unmet Need Cancers

- Initial focus in post-ICI solid tumors
- Expansion into combinations, new tumor types, earlier lines of therapy and genetic modifications
- Key late-stage trials in melanoma, NSCLC
- First-in-human trial of genetically modified PD-1 inactivated TIL

First FDA Approved T Cell Therapy for a Solid Tumor Cancer

- FDA accelerated approval for Amtagvi™ in advanced melanoma
- TILVANCE-301 Phase 3 confirmatory trial in frontline advanced melanoma (FTD)
- Defined registration strategy in NSCLC

Efficient and Scalable Proprietary Manufacturing Facility

- Iovance Cell Therapy Center (iCTC) in-house manufacturing
- Ample capacity for U.S. launch and global clinical trials
- Additional capacity with contract manufacturer

Fully-In-Commercial

- Experienced function therapy
- TIL service established U.S. centers
- Iovance proprietary



IOVANCE
BIOTHERAPEUTICS

Thank You

ADVANCING IMMUNO-ONCOLOGY

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