**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): February 28, 2024

# 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 February 28, 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 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 - February 28, 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: February 29, 2024

**IOVANCE BIOTHERAPEUTICS, INC.**

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

Exhibit 99.1


IOVANCE
BIOTHERAPEUTICS
Corporate Overview
February 28, 2024
ADVANCING IMMUNO-ONCOLOGY
© 2024, Iovance Biotherapeutics, Inc.

# Forward-Looking Statements

Certain matters discussed in this press release are "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "
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 o
convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions a
made in light of management's experience and perception of historical trends, current conditions, expected future developments, and other factors believed to be a
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
information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties, and other fact
are outside of our control, that may cause actual results, levels of activity, performance, achievements, and developments to be materially different from those expr
these forward-looking statements. Important factors that could cause actual results, developments, and business decisions to differ materially from forward-lookin
described 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-
Reports 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 re
successfully commercialize our products, including AMTAGVI, for which we obtain U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA")
authority approval; the risk that the EMA or other regulatory authorities may not approve or may delay approval for our biologics license application ("BLA") submiss
metastatic melanoma; the acceptance by the market of our products, including AMTAGVI, and their potential pricing and/or reimbursement by payors, if approved (i
product candidates), in the U.S. and other international markets and whether such acceptance is sufficient to support continued commercialization or developmen
including AMTAGVI, or product candidates, respectively; our ability or inability to manufacture our therapies using third party manufacturers or at our own facility ma
commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk rega
integration of the recent Proleukin acquisition; the risk that the successful development or commercialization of our products, including AMTAGVI, may not generate
from product sales, and we may not become profitable in the near term, or at all; the risk that future competitive or other market factors may adversely affect the co
AMTAGVI; the risks related to the timing of and our ability to successfully develop, submit, obtain, or maintain FDA, EMA, or other regulatory authority approval of, or
respect to, our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authoritie
registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities, including the risk that the planned single arm Phase 2 IOV-LUN-20
support registration; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflecte
of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; the risk that enrollment may need to be adjusted for our trials and coho
based on FDA and other regulatory agency input; the risk that the changing landscape of care for cervical cancer patients may impact our clinical trials in this indicat
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; t
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 resul
communications by such regulatory authorities (including from our prior meetings with the FDA regarding our non-small cell lung cancer clinical trials); the risk that
ongoing clinical trials of AMTAGVI will not continue or be repeated in ongoing or planned clinical trials or may not support regulatory approval or renewal of authoriz
unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; the effects of the COVID-19 pa
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

## Platform

**700+**
Clinical Trial Patients Treated with Iovance TIL Products

**2**
Manufacturing Sites FDA Approved for Commercial Production

**22-day**
Proprietary Manufacturing Process

## Portfolio

**2** Commercial Products
AMTAGVI (lifileucel) PROLEUKIN (aldesleukin)

**7** Active Clinical Trials

**5** Tumor Types in Clinic

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

## People & Assets

**~$485M**
Cash Position as of 2/22/24[1]

**60+**
US and International Patents

**500+**
Employees

1. Unaudited cash position which includes net proceeds of approximately $197.1 million from a follow-on equity financing in February of 2024.
Abbreviations: BTD=Breakthrough Therapy Designation; FDA=U.S. Food and Drug Administration; RMAT=Regenerative Medicine Advanced Therapy Designation

# Iovance Solid Tumor Portfolio Highlights

AMTAGVI™ (lifileucel) Suspension for IV infusion

***Post-anti-PD-1 advanced melanoma***
***NOW APPROVED***

PROLEUKIN® (aldesleukin) Recombinant IL-2

***AMTAGVI treatmen***
*Advanced melanoma, r*

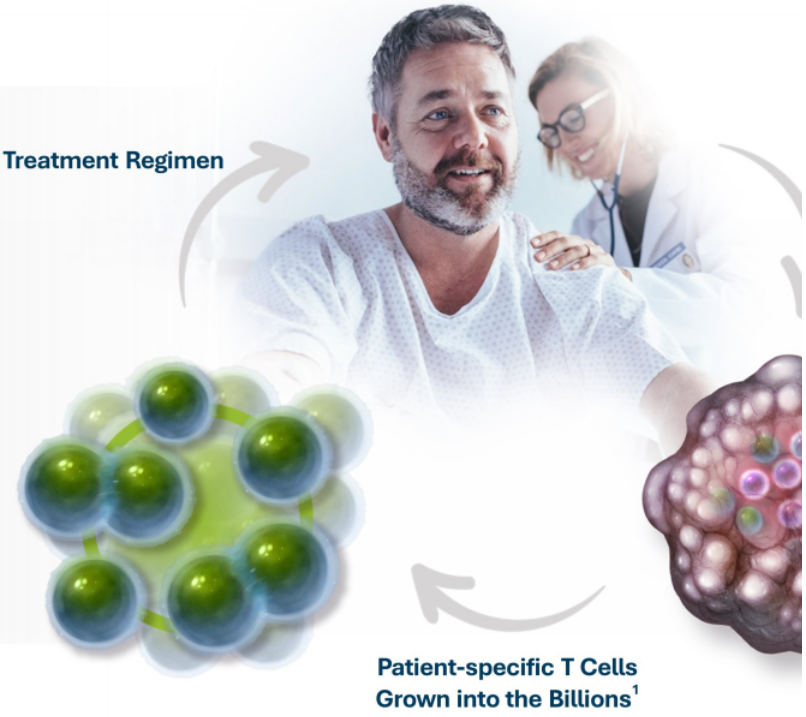
| | CANDIDATE | INDICATIONS | PHASE 1 | PHASE 2 |
|---|---|---|---|---|
| **Registration-Directed** | Lifileucel + pembro | Frontline advanced melanoma | TILVANCE-301 Phase 3 | |
| | LN-145 | 2L post-chemo & post-anti-PD-1 advanced NSCLC | IOV-LUN-202: Cohorts 1&2 | |
| | Lifileucel | Post-chemo & post-anti-PD-1 cervical | C-145-04: Cohort 2 | BTD, ODD |
| **Additional Pipeline** | LN-145 + pembro | 1L chemo and anti-PD-1 naïve cervical | C-145-04: Cohort 3* | |
| | Lifileucel | 2L post-chemo & post-anti-PD-1 endometrial | *Planned Phase 2* | |
| | LN-145, LN-145 + ICI | 2-4L incl. post-anti-PD-1 advanced NSCLC | IOV-COM-202: Cohorts 3A, 3B*,3C | |
| | LN-145 + ICI | 1L advanced melanoma | IOV-COM-202: Cohort 1A | |
| **Next Generation** | 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 | |
| | LN-145 Gen 3 + core biopsy | 2L post-chemo & post-anti-PD-1 advanced NSCLC | IOV-LUN-202: Cohort 3 | |

*Enrollment complete
Abbreviations: 1L=first line; 2L=second line; 4L=fourth line; BTD=Breakthrough Therapy Designation; FTD=Fast Track Designation; ipi/nivo=ipilimumab/nivolumab; NSCLC=non-small cell lung cancer; ODD=Orphan Drug Designation; PD-1=programmed cell death protein-1; RMAT=Regenerative Medicines Advanced Therapy; 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




1. AMTAGVI USPI

# AMTAGVI™ (lifileucel):
# First and only one-time, individualized T cell therap
# approved by FDA for a solid tumor cancer

Actor portrayal and not a real image of a T cell.

1. AMTAGVI USPI

**NOW APPROVED**

# The first and only FDA-approved therapy for previously treated a (unresectable or metastatic) me

*AMTAGVI™ is a one-time treatment unique for each patient.*

## Indication

AMTAGVI (lifileucel) is a tumor-derived autologous T cell immunotherapy indicated for the treatmer unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRA a BRAF inhibitor with or without a MEK inhibitor.

This indication is approved under accelerated approval based on objective response rate (ORR). Co indication may be contingent upon verification and description of clinical benefit in a confirmator

## Important Safety Information

WARNING: TREATMENT-RELATED MORTALITY, PROLONGED SEVERE CYTOPENIA, SEVERE INFECTION, RENAL IMPAIRMENT

- Monitor patients for prolonged severe cytopenia and monitor for internal organ hemorrhage
- Administer filgrastim or a biosimilar product to patients beginning Day 1 after AMTAGVI and co absolute neutrophil count (ANC) is greater than 1000 per $mm^3$ for 3 consecutive days, or per in
- Treat severe infections
- Monitor cardiopulmonary and renal functions throughout the treatment course

Administer in an inpatient hospital setting. An intensive care facility and specialists skilled in car care medicine must be available.

# U.S. Unmet Medical Need for Metastatic Melanoma Therap

AMTAGVI is the First FDA Approved Treatment Option After Progression on ICI (Anti-PD-1) Therapy and BRA inhibitors

**15k**

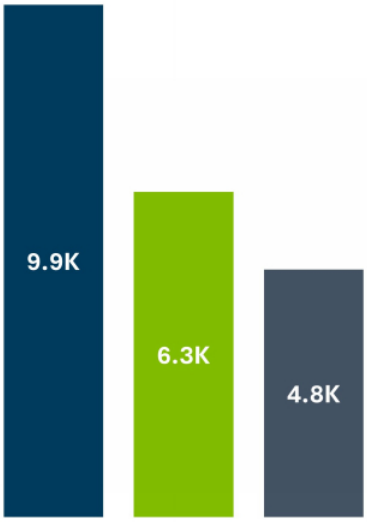
**Annual new cases of advanced melanoma in U.S.[1]**

**8k**

**Annual deaths in U.S.[2]**

**Melanoma Drug-Treated Population in 2021**

Unresectable / Metastatic (US) [3]




**High unmet ne who progress checkpoin**

More than ha progress **with** on curren regardles mutatio

1. Estimate of US incidence (2021) of unresectable or metastatic melanoma based on secondary and primary market research
2. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. https://seer.cancer.gov accessed February 2024
3. Clarivate DRG Disease Landscape (2021)
4. 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; PD-1=programmed cell death protein-1

# AMTAGVI™ Delivered Deep and Durable Responses

**Cohort 4 Pivotal[1] (N=73)**

**ORR 31.5%**
(95% CI: 21.1, 43.4)

**mDOR Not Reache**
**18.6 months follow**
(Range: 1.4+, 26.3+; 95% CI

**Supportive Pooled Data[1] (n=153)**

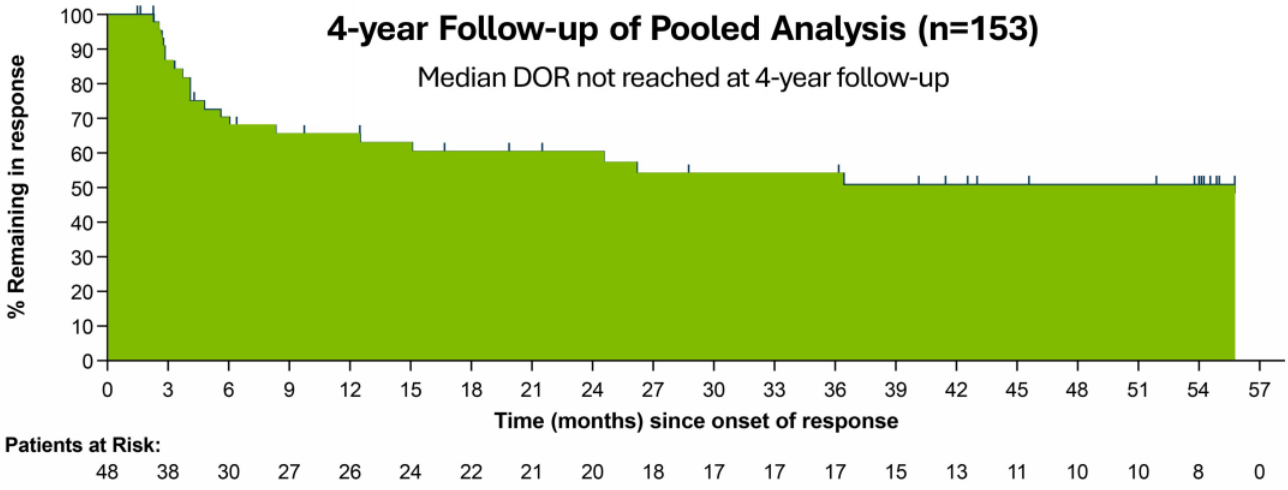
**ORR 31.4%**
(95% CI: 24.1, 39.4)

**mDOR Not Reached**
**21.5 months follow**
(Range: 1.4+,

1. AMTAGVI USPI
2. Data on file.

CI, confidence interval; mDOR, median duration of response; NR, not reached.

# AMTAGVI™ C-144-01 4-year Follow Up




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

ORR

mDOR

48.1

1. Medina et al, ESMO IO 2023.

# AMTAGVI™ Patient Journey

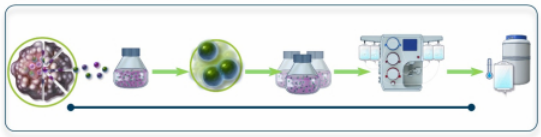
## AMTAGVI Autologous T Cell Therapy

**Treatment Decision & Reimbursement Approval**

**Scheduling & Tumor Tissue Procurement**

AMTAGVI starts with a piece of the patient's tumor tissue

**T Cell Therapy Manufacturing & Release Testing**



TIL cells are grown into the billions in a manufacturing facility

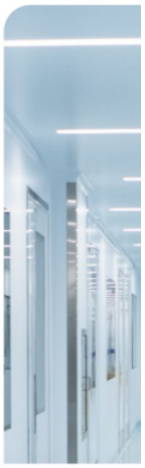
**Treatment Reg & Monitori**

- Lymphodepl
- **AMTAGVI™ (**
- Short-Cours

# Iovance Cell Therapy Center: *i*CTC

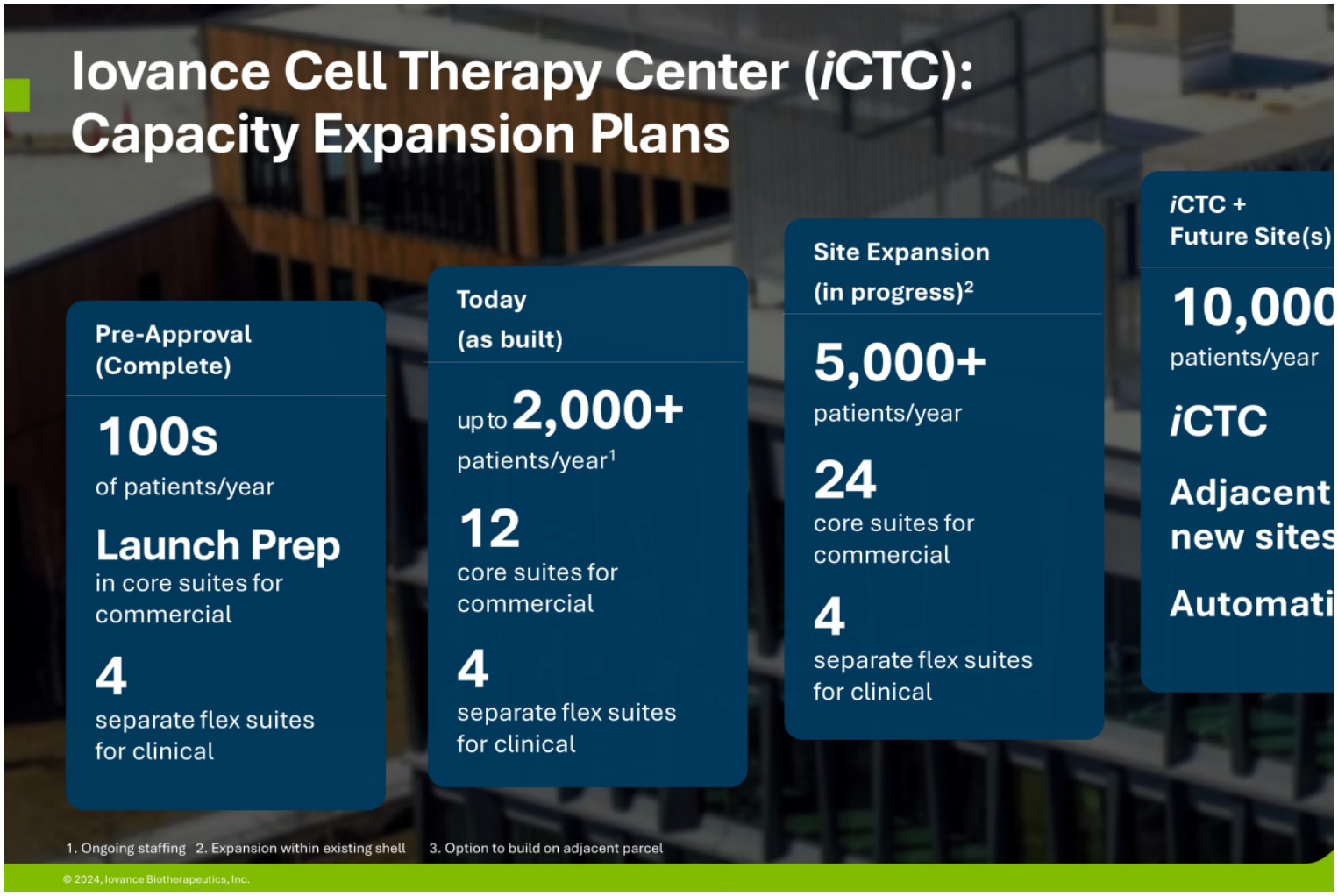
- Built-to-suit custom facility in Navy Yard Philadelphia
- Annual capacity for up to several thousand patients as built
- Expansion underway for additional capacity within iCTC over next few years
- Additional CDMO capacity
- Control to optimize capacity, quality & COGS

## FDA-Approved Cell Therapy Manufacturing Facili
## Dedicated to Commercial and Clinical TIL Cell Ther



IOVANCE BIOTHERAPEUTICS
CELL THERAPY CENTER

FOYA 2
ISPE Facility of the Year Awa
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 + Future Site(s)
10,000
patients/year
iCTC
Adjacent new sites
Automati
1. Ongoing staffing 2. Expansion within existing shell 3. Option to build on adjacent parcel
© 2024, Iovance Biotherapeutics, Inc.

# Proleukin® (aldesleukin) Strategic Benefits

Global Rights Acquired in May of 2023

- Significant revenue anticipated with AMTAGVI™ launch
- IL-2 supply chain secured for AMTAGVI regimen
- Lower clinical trial costs and COGS anticipated

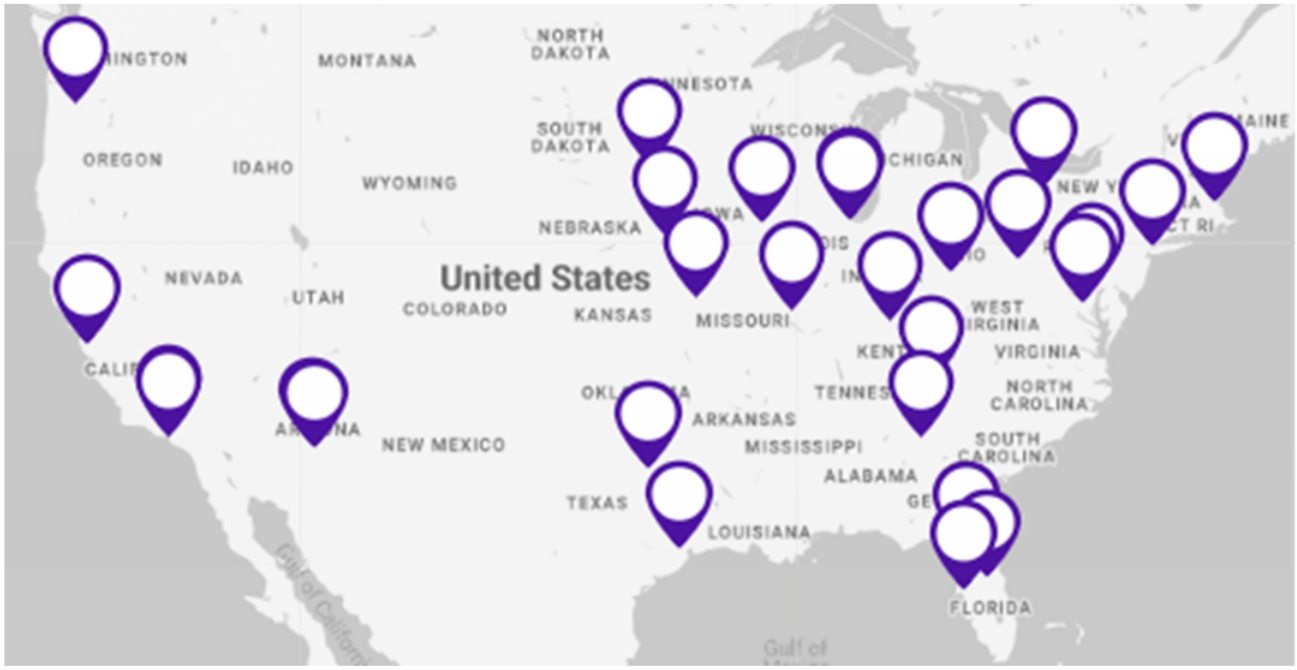
PROLEUKIN®
(aldesleukin) Recombinant IL-2

Short course Pr
administered after
promote T cell grow

Key Transaction
£167.7M
£41.7M

# Targeting Potential Authorized Treatment Centers (ATCs)

30 Active ATCs at Approval; ~50 ATCs Expected 90 Days Post-PDUFA




**Targeting Consider**

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

**Drive Der**

- Top acco
- Commur

1. Amtagvi.com (Last accessed February 28, 2024)

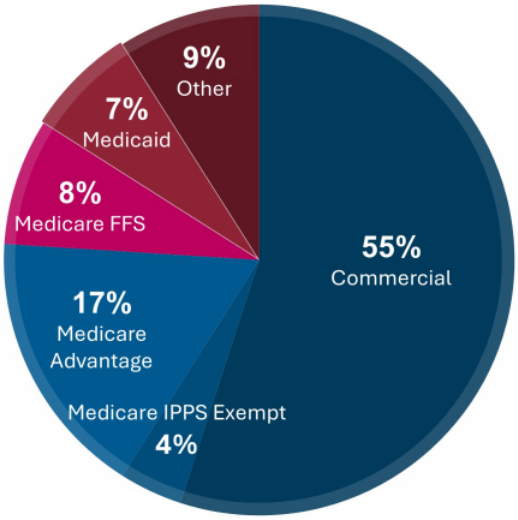
Abbreviations: ATC=Authorized Treatment Centers; NCCN=National Comprehensive Cancer Network; KOL=Key Opinion Leaders; BMT=Bone Marrow Transplant

# Market Access

Payers appreciate the high unmet need, lack of treatment options, and AMTAGVI clinical value

## Metastatic Melanoma Payer Mix[1]

All Treatment Settings and Lines of Therapy

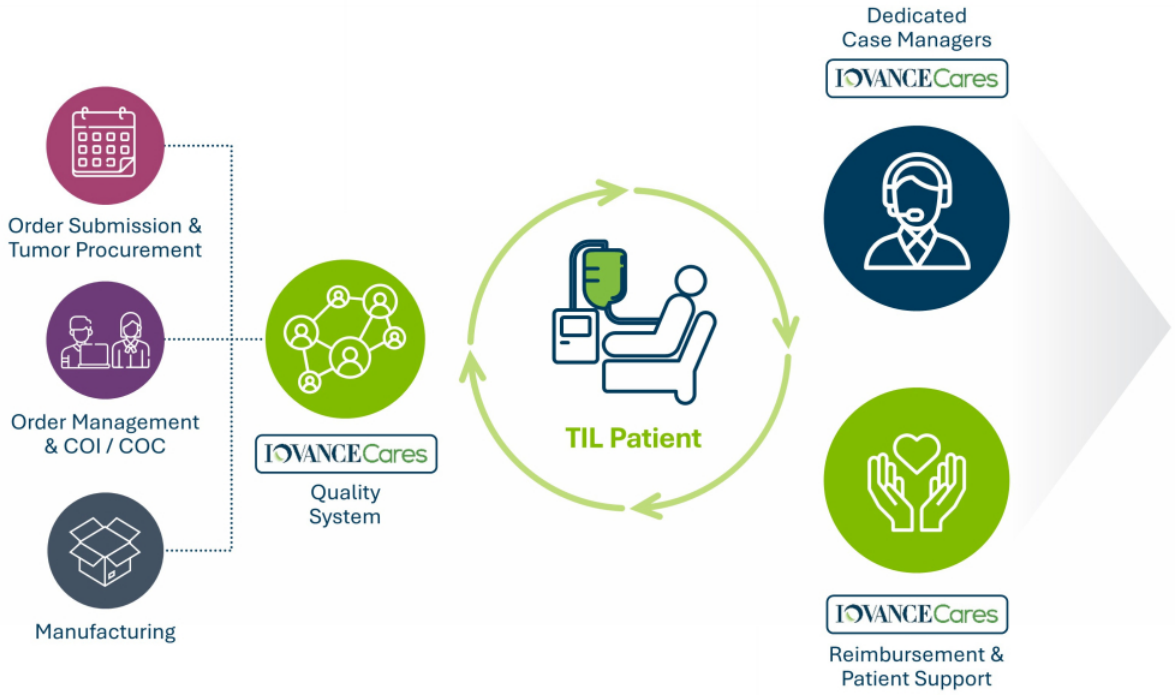



## Anticipated Access

- Engagement with payers respo
  ~90% of covered lives
- Strong hospital reimbursement
  - Inpatient payment methodolog
    established
  - Key payers expected to reimbu
    provider costs
- Expect similar coverage to C

1. Metastatic Melanoma Insurance Claims Analysis, TIL-eligible patients treated in the ATC setting(1/1/2018–6/30/2021). Medicaid is 6% Medicaid Advantage and 1% Medicaid Fee-For-Service;
For the 12% Medicare FFS lives, 11 PPS-exempt hospitals are reimbursed by Medicare FFS on a cost-basis (~4%), with the remaining Medicare FFS lives (~8%) reimbursed under DRG-018 payment methodology, NTAP/Outlier payments may add to the total Medicare reimbursement. Other segment includes cash, self-insured, VA, and other unidentifiable claims.
Abbreviations: FFS=Fee-For-Service; ICD-10 PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; NTAP = New Technology Add-on Payment

# Supporting Providers & Patients: IovanceCares™




**Customer-Cen**

- Patient managen
- Proprietary COI/(
- Treatment cente

**Patient-Centric**

- Dedicated case r
- Reimbursement
- Patient support p

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

# AMTAGVI™ Expansion Plans in Advanced Mela

# Ex-U.S. Unmet Medical Need for Metastatic Melanoma The

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

## Preparing for EU MAA and Additional Ex-U.S. Submissions in 2024

**57k**

**Annual deaths worldwide[1]**

**15k**

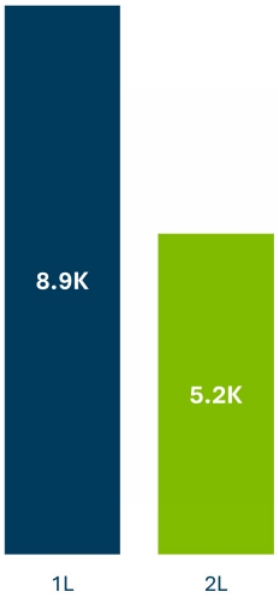
**Annual deaths in ex-U.S. target markets[1]**

### Annual Deaths from Melanoma in Target Ex-U.S. Markets[1]

| | | | |
|---|---|---|---|
| **3.2K** | Germany | **1.4K** | Australia |
| **2.8K** | UK | **1.2K** | Canada |
| **2.2K** | Italy | **1.1K** | Spain |
| **2.1K** | France | **0.9K** | Netherlands |

### Melanoma Drug-Treated I

Unresectable / Meta



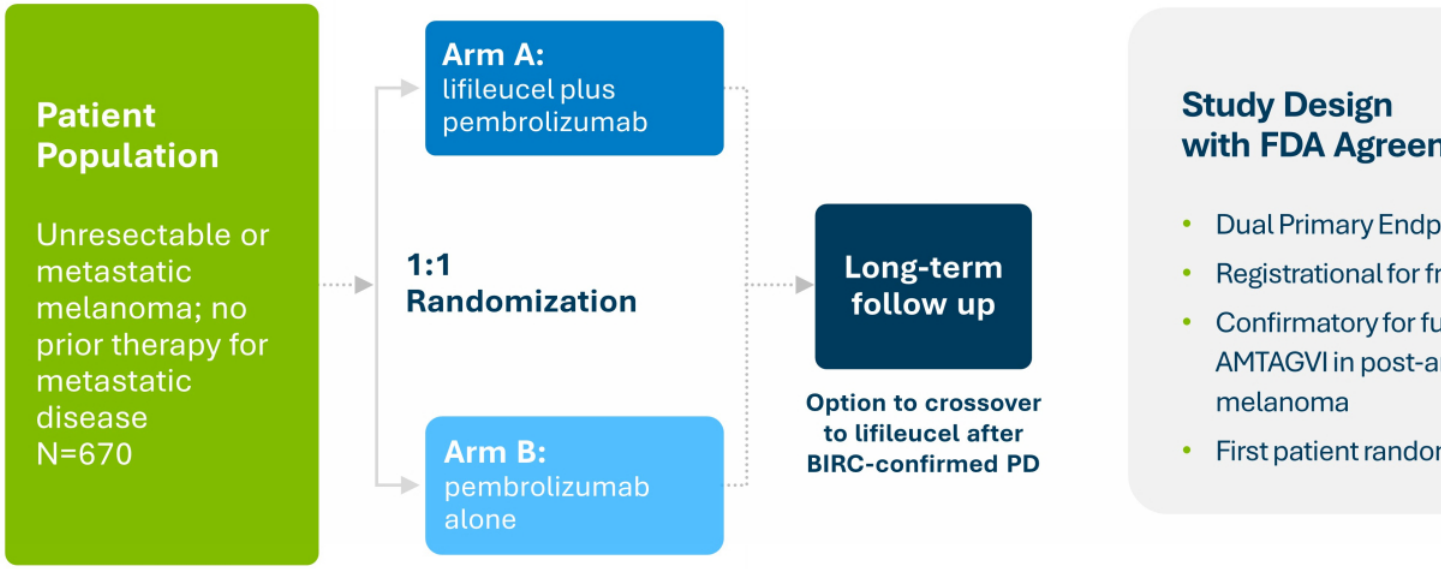

1. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2020
2. Clarivate DRG Disease Landscape (2021)

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

LIFILEUCEL + PEMBROLIZUMAB IN FRONTLINE ADVANCED MELANOMA

# TILVANCE-301 Global Phase 3 and Confirmatory Trial

Randomized, multicenter study with optional crossover to offer all patients potential to receive lifileucel (N




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

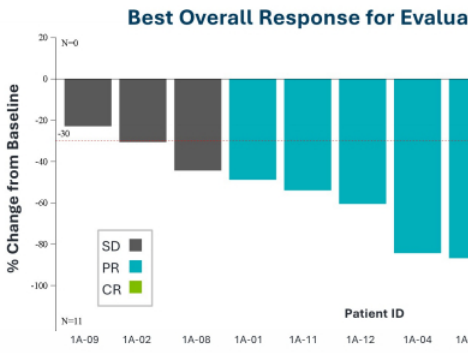
IOV-COM-202 COHORT 1A MELANOMA COMBINATION (TIL+PEMBROLIZUMAB)

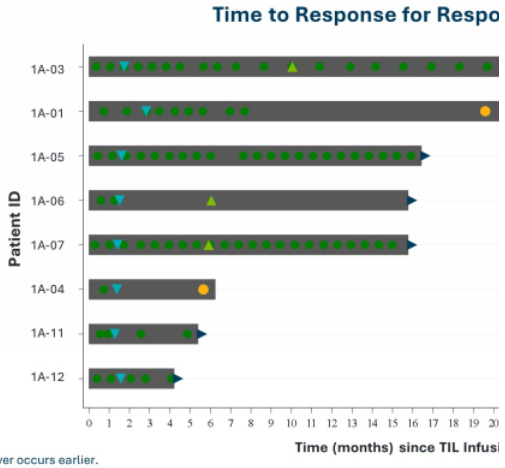
# Iovance TIL Clinical Highlights in Combination with Pembrolizumab in Metastatic Melanoma

**Lifileucel in combination with anti-PD-1/PD-L1 therapy in ICI-naïve patients**
(IOV-COM-202 Cohort 1A, N=12)[1]

## 66.7% ORR

- 8 / 12 patients had a confirmed objective response per RECIST v1.1 (3 CRs & 5 PRs)
- 6 / 8 responders had ongoing response
- 5 responders had DOR >1 year
- FDA Fast Track Designation




1. As assessed by investigator using RECIST 1.1 (January 20, 2022 data cutoff)
2. 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: CR=complete response; ICI=immune checkpoint inhibitor; ORR=objective response rate; PR=partial response; SD=stable disease; pembro=pembrolizumab; RECIST=Response Evaluation Criteria in Solid Tumors

# TIL Therapy Pipeline

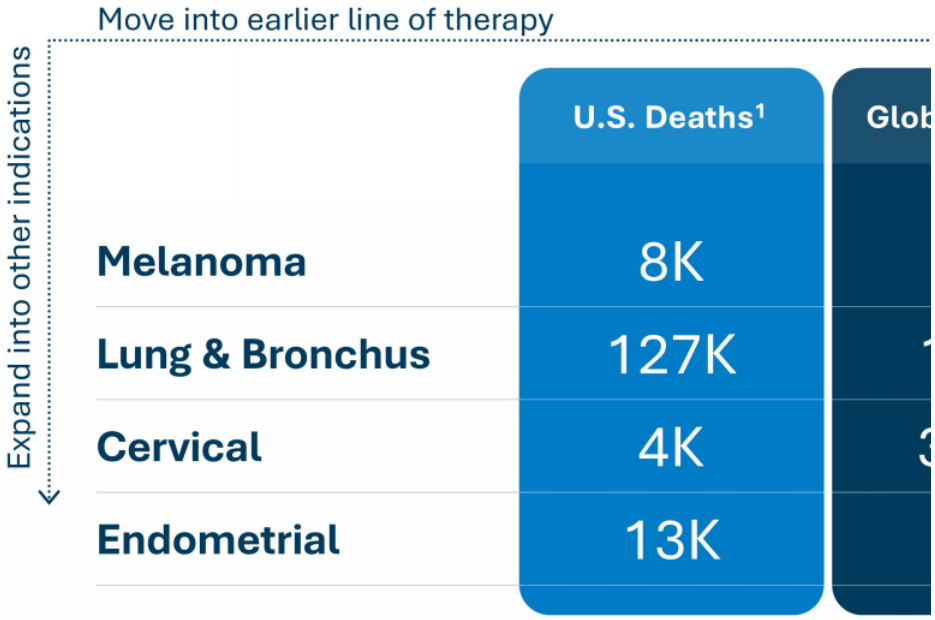
# Significant Market Potential in Solid Tumors and our Key Pr

**91%**

of all cancer cases are solid tumors[1]

**1.8M**

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




1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. https://seer.cancer.gov accessed February 2024
2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2020

# Potential Market for Advanced Non-Small Cell Lung Cancer (NS

Addressing a Substantial Unmet Need in Metastatic NSCLC

## Iovance TIL clinical program:

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

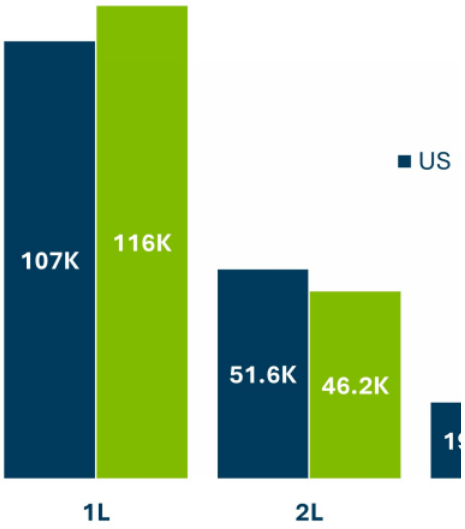
**127K annual deaths in U.S.**[1]

Leading cause of U.S. cancer deaths, accounting for ~1 in 5 cancer-related deaths[2]

9% 5-year survival rate[2] and real-world overall survival <6 months[3] in U.S.

**NSCLC Drug-Treated Popul**

Stage IV (US and EU

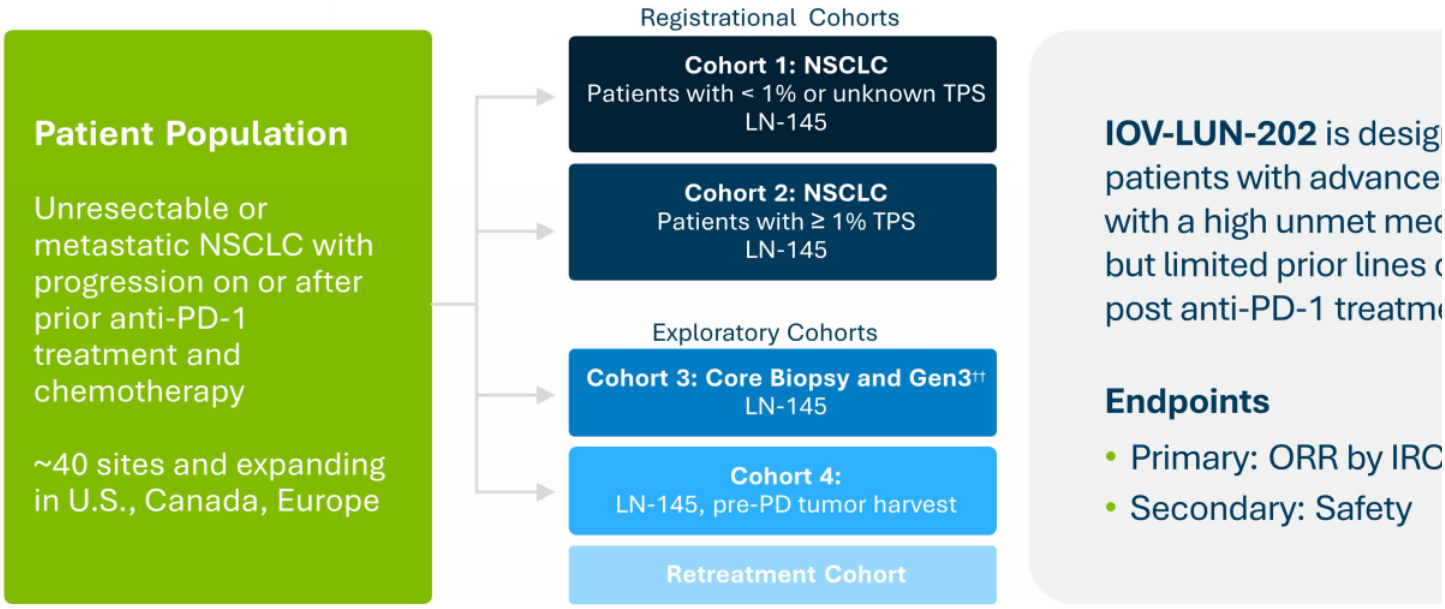



1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. https://seer.cancer.gov accessed February 2024
2. American Cancer Society, Lung Cancer. https://www.cancer.org/cancer/types/lung-cancer/about.html accessed July 2023
3. National Cancer Database, NSCLC 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 United Kingdom; 1L=first line therapy, 2L=second line therapy, 3L=third line therapy, 4L=fourth line therapy; mOS=median overall survival

# IOV-LUN-202 Trial Design

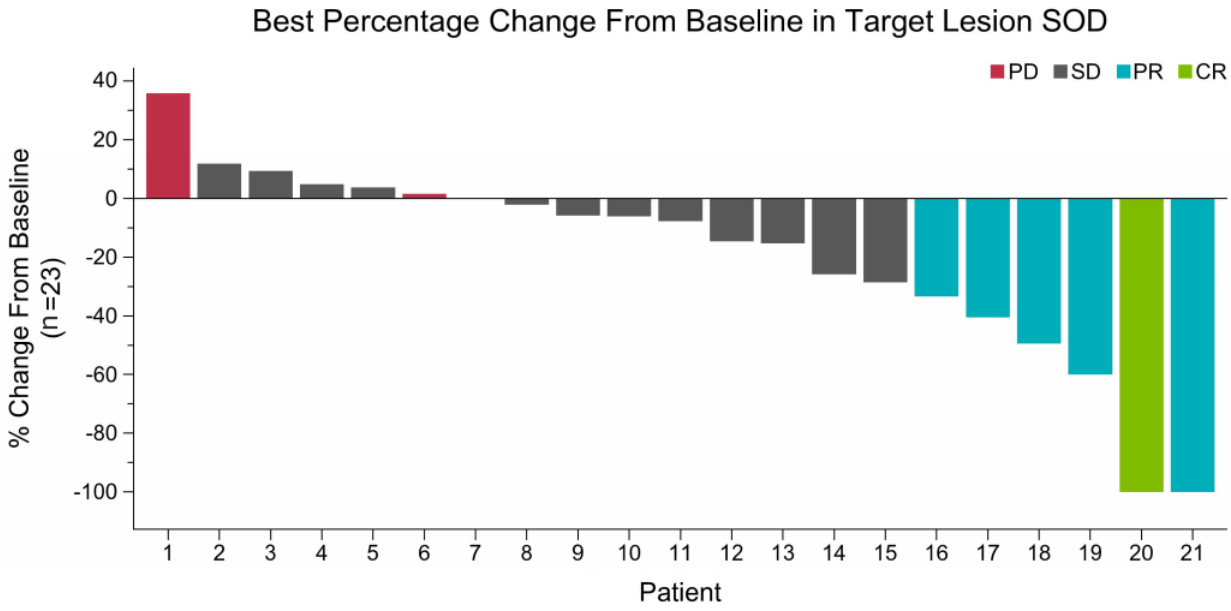
Phase 2 Multicenter Study of LN-145† in Patients Post-Anti-PD-1 NSCLC (NCT04614103)*




* U.S. FDA placed a partial clinical hold on the IOV-LUN-202 trial on December 22, 2023. Enrollment for new patients is paused. Patients previously treated continue to be monitored and followed. Patients who have already undergone tumor resection will continue to receive the LN-145 TIL treatment regimen with additional precautions and risk mitigations..
†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

## 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

## 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) |

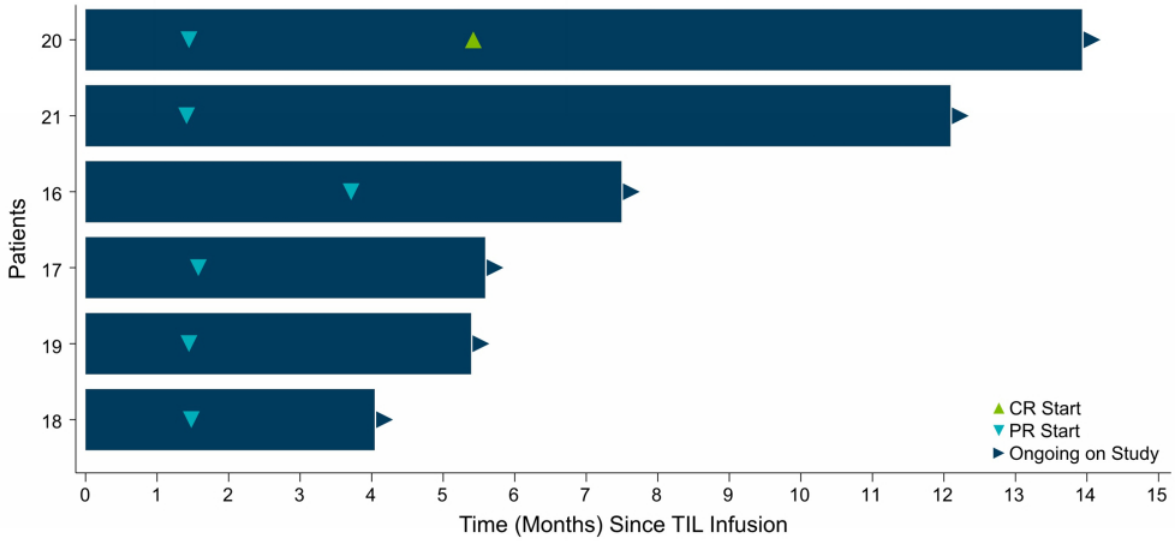
TEAEs were consistent with the underlying disease and known AE profiles of NMA-LD and IL-2

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

## 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 LN-145 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.

# Cohort 3A Summary

## Proof-of-Concept for TIL in ICI-Naïve NSCLC Regardless of PD-L1 Status


### Clinical Activity at 18.2 Months of Follow Up[1,2]

- Activity across ICI naïve subgroups and TPS Scores
- 58.3% (7/12) ORR and 3 ongoing responses in NSCLC patients with $EGFR^{WT}$ disease
- Safety consistent with Iovance TIL combination studies
- Supports proposed registrational trial design in patients with $EGFR^{WT}$ disease in the frontline setting

Cohort 3A Results Support A
Therapy to Frontline Pembroli
Chemotherapy Combination F

1. Schoenfeld, et al. WCLC 2023
2. Data cut: June 26, 2023

Abbreviations: cy/flu, cytarabine/fludarabine; EGFR, epidermal growth factor receptor; ICI, immune checkpoint inhibitor; IL-2, interleukin-2; NMA-LD, non-myeloablative lymphodepletion; TPS, tumor proportion score; WT, wild type

# Frontline NSCLC Registrational Trial: Design Supported by Cohort

## Adding TIL Therapy to Standard-of-Care Therapy

**Patient Population**

Treatment naïve metastatic NSCLC

EGFR$^{WT}$ Disease

All PD-L1 TPS Scores

**SOC Chemo-IO Treatment***

**SOC Maintenance Treatment +/- TIL**

**Long Follo**

**Experimental Arm**

**Chemotherapy** Platinum Doublet

**TIL**

**Pembrolizumab**

**Comparator Arm**

**Chemotherapy** Platinum Doublet

**Pembrolizumab**

- FDA mee discuss be regist treatmer NSCLC p
- Confirma accelera post anti

| Benchmarks | EGFR/ALK status | ORR | mDOR (mos) | mPFS (mos.) | Prior IO | Prior Chemo | PD-L1 (%) | SQ or NSQ |
|---|---|---|---|---|---|---|---|---|
| Keynote-189[1,2] | WT | 48% | 11.2 | 8.8 | No | No | All | NSQ |
| PD-L1 <1 Subgroup[1,2] | WT | 32% | | | No | No | <1 | NSQ |
| Keynote-407[1] | N/A | 58% | 7.2 | 6.4 | No | No | All | SQ |

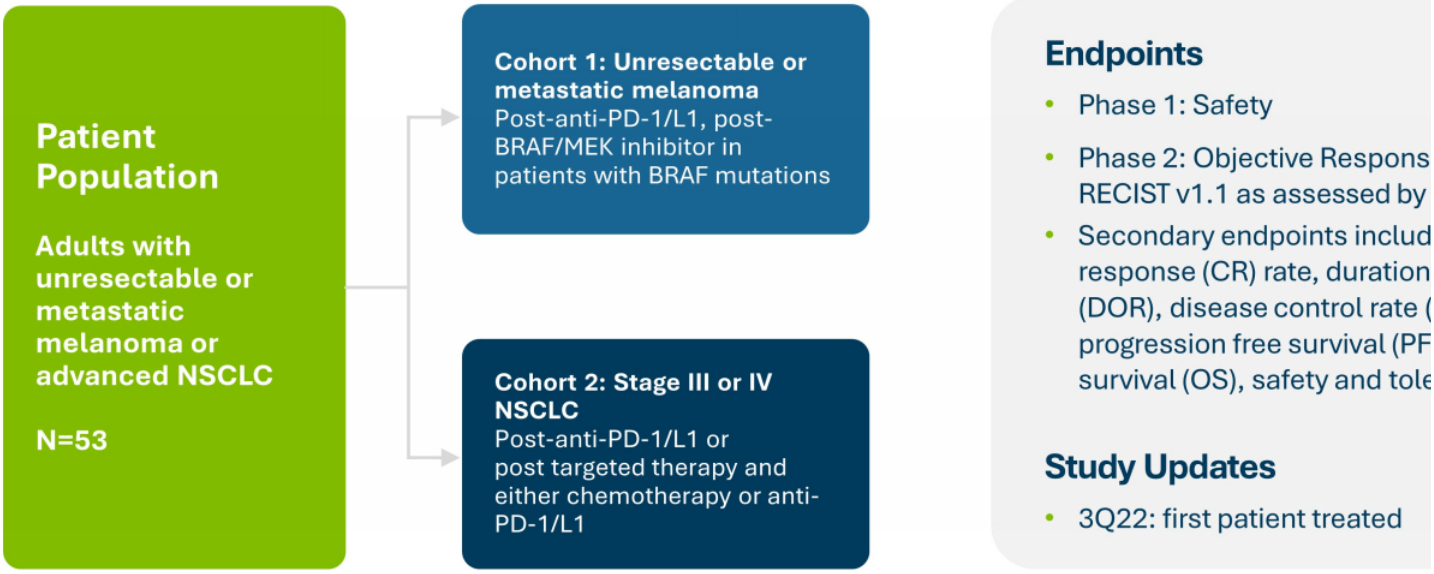
* SOC Chemo-IO is 4-6 cycles of pembro + platinum-based chemotherapy doublet

1. KEYTRUDA USPI
2. Ghandi et al, NEJM 2018

NEXT-GENERATION TIL THERAPY IOV-4001

# 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 a
(NCT05361174)




NSCLC=non-small-cell lung cancer

# Trailblazing Next-Generation TIL Programs

| Genetically modify TIL | Optimize TIL composition | Next-generation processes | Exp ne |
|---|---|---|---|
| Cellectis gene-editing TALEN® collaboration[1,2] | PD-1+ selected TIL | Gen 3 (16-day) process | IO ana from ena |
| PD-1 and other immune checkpoint targets (single and multiple knockouts) | CD39/69 double negative TILs[3] | Core biopsy | |
| Cytokine-tethered TILs | | | |

# Corporate Summary & Milestones

# Well-Capitalized in Pursuit of TIL Commercialization

| February 22, 2024 | (in millions) |
|---|---|
| Cash, cash equivalents, investments, restricted cash | $485.2[1] |
| Common shares outstanding | 279.3 |
| Preferred shares outstanding | 2.9[2] |
| Stock options and restricted stock units outstanding | 22.0 |

**Cash runway is sufficient well into second half of 2025[3]**

1. Unaudited cash position which includes net proceeds of approximately $197.1 million from a follow-on equity financing in February of 2024. Includes Restricted Cash of $66.4 million.
2. Preferred shares are shown on an as-converted basis
3. Includes anticipated revenue from Amtagvi™ and Proleukin®

# 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-US 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 US and ex-US demand

**COMMERCIAL**

- ☐ Execute commercial launch (1Q24)
- ☐ On-board 50 ATCs within 90 days of PDUFA date

# Corporate Highlights

## Pioneering a Transformational Approach to Cure Cancer

### Large Market Opportunity in High Unmet Need Cancers

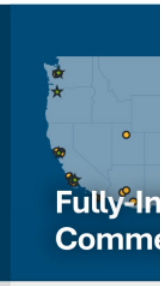
- Initial focus in post-ICI solid tumors
- Expansion into combinations, earlier lines of therapy and genetic modifications
- Key late-stage trials in melanoma, NSCLC and cervical cancer
- First-in-human trial of genetically modified PD-1 inactivated TIL

### 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 and cervical cancer (BTD)

### Efficient and Scalable Proprietary Manufacturing Facility

- Iovance Cell Therapy Center (*i*CTC) in-house manufacturing
- Additional capacity with contract manufacturers
- Rapid 22-day Gen 2 manufacturing
- >700 patients treated with Iovance proprietary process



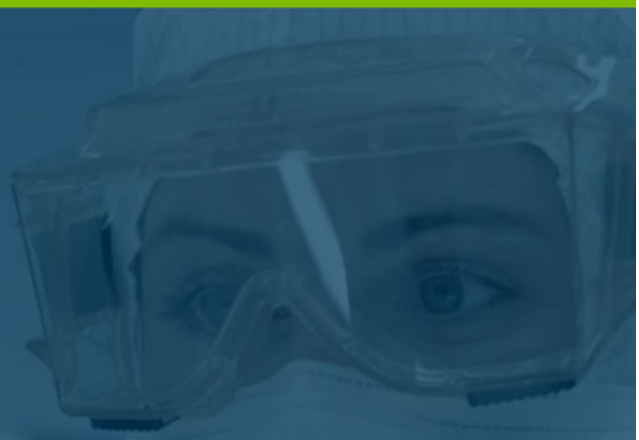
### Fully-In Comme

- Experie functio therapy
- TIL serv establis U.S. ca
- Iovance proprie



Abbreviations: BLA, Biologics License Application; BTD, breakthrough therapy designation; FTD, fast track designation; ICI, immune checkpoint inhibitor; NSCLC, non-small cell lung cancer; PD-1, programmed cell death protein-1; RMAT, Regenerative Medicines Advanced Therapy; TIL, tumor infiltrating lymphocytes.

IOVANCE BIOTHERAPEUTICS



# Thank You

ADVANCING IMMUNO-ONCOLOGY