

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): August 16, 2023

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, 4th Floor
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 share | IOVA | The Nasdaq Stock Market, LLC |

Item 7.01. Regulation FD Disclosure.

On August 16, 2023, Iovance Biotherapeutics, Inc. (the “Company”) announced that the International Association for the Study of Lung Cancer (“IASLC”) inadvertently posted the following presentation (the “presentation”) on the IASLC’s 2023 World Conference on Lung Cancer website on the morning of August 16, 2023:

- “Multicenter Phase II Trial Of LN-145 TIL Cell Therapy Plus Pembrolizumab in Patients With ICI-Naïve Metastatic NSCLC”

Such posting by IASLC, ahead of the Company’s planned disclosure in connection with the conference, was not authorized by the Company. In response to such unauthorized posting by IASLC, the Company immediately made the presentation available on its website on August 16, 2023. The presentation is attached as Exhibit 99.1 hereto and incorporated herein by reference.

The information furnished under this Item 7.01, including the accompanying Exhibit 99.1, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of such section, nor shall such information be deemed to be incorporated by reference in any subsequent filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language of such filing, except as specifically stated in such filing.

Item 8.01 Other Events.

On August 16, 2023, 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 99.2 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|----------------------|--|
| 99.1 | Presentation titled “Multicenter Phase II Trial Of LN-145 TIL Cell Therapy Plus Pembrolizumab in Patients With ICI-Naïve Metastatic NSCLC” |
| 99.2 | Iovance Biotherapeutics, Inc., Corporate Presentation - August 2023 |
| 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: August 18, 2023

IOVANCE BIOTHERAPEUTICS, INC.

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



2023 World Conference
on Lung Cancer

SEPTEMBER 9-12, 2023 | SINGAPORE



Multicenter Phase II Trial Of LN-145 TIL Therapy Plus Pembrolizumab in Patients ICI-Naïve Metastatic NSCLC



Adam Schoenfeld¹; Kai He²; Jason Chesney³; Edward Garon⁴; Jorge Ni
Adrian Sacher⁶; Sylvia Lee⁷; Friedrich Graf Finckenstein⁸; Rana Fiaz⁸;
Melissa Catlett⁸; Guang Chen⁸; Viktoria Gontcharova⁸; Benjamin C. Cr

¹Memorial Sloan Kettering Cancer Center, New York, NY, USA; ²James Cancer Center, The Ohio State University, Columbus, OH, USA;
³James Graham Brown Cancer Center, University of Louisville, Louisville, KY, USA; ⁴University of California Los Angeles, Los Angeles, CA, US.
⁵University of Southern California, Los Angeles, CA, USA; ⁶Princess Margaret Cancer Centre, Toronto, Ontario, Canada; ⁷Fred Hutchinson
Cancer Center, Seattle, WA, USA; ⁸Iovance Biotherapeutics, Inc., San Carlos, CA, USA; ⁹H. Lee Moffitt Cancer Center and Research Institute,
Tampa, FL, USA

Adam Schoenfeld, Memorial Sloan Kettering Cancer Center, New York, NY, USA

IOV-COM-202 3A: LN-145 + anti-PD-1 in ICI-naïve mNSCLC

Merging Potent Immunotherapy Modalities

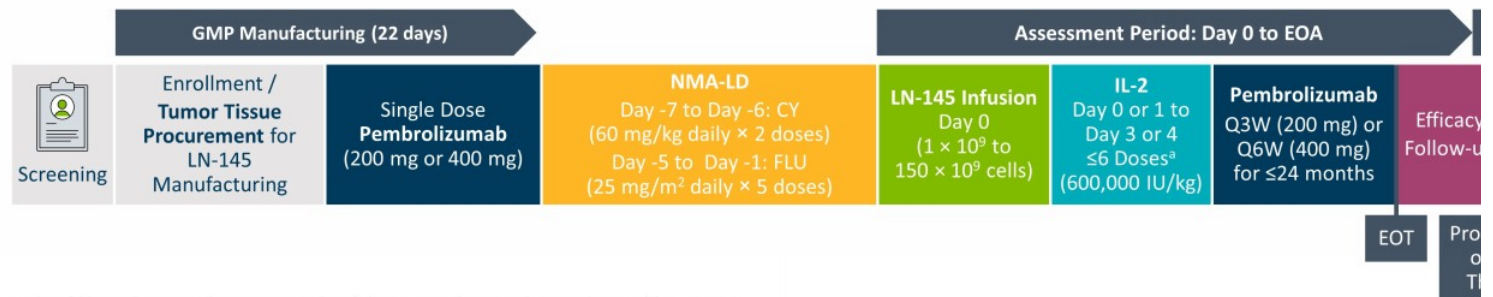
Introduction

- Benefit from front-line ICI ± chemotherapy in patients with mNSCLC is limited by primary and secondary resistance
- TIL cell therapy has produced durable objective responses in patients with extensively pretreated mNSCLC^{1,2}
- Integration of TIL cell therapy in front-line regimens may improve long-term benefit

Methods and Objective

- IOV-COM-202 (NCT03645928) is a global, phase 2, multic open-label study of autologous TIL cell therapy in patient
- Cohort 3A includes patients with anti-PD-1/PD-L1 naïve metastatic NSCLC with disease progression
- We report data for patients in Cohort 3A treated with LN-pembrolizumab (**Figure 1**)

Figure 1. Treatment Regimen and IL-2 Dosing



1. Schoenfeld A, et al. *J Immunother Cancer* 2021;9(Suppl 2):A458. 2. Creelan BC, et al. *Nat Med* 2021;27(8):1410–1418.

*Every 8–12 hours (3–24 hours after completion of LN-145 infusion).

CY, cyclophosphamide; EOA, end of assessment; EOS, end of study; EOT, end of treatment; FLU, fludarabine; GMP, Good Manufacturing Practice; ICI, immune checkpoint inhibitor; IL-2, interleukin-2; IU, international units; mNSCLC, metastatic small cell lung cancer; NMA-LD, non-myeloablative lymphodepletion; PD-1, programmed cell death protein 1; PD-L1, programmed death ligand-1; TIL, tumor-infiltrating lymphocyte.

Results: Baseline Demographics and Safety Data

Majority of Patients Were PD-L1–Negative With High Disease Burden

Table 1. Baseline Patient and Disease Characteristics

| Characteristics | Cohort 3A (N=19) |
|--|------------------|
| Median age, y (min, max) | 55.4 (35, 68) |
| Never tobacco use, n (%) ^a | 7 (36.8) |
| Median prior lines of systemic therapy by prior therapy subgroup, n (min, max) | 1 (0, 4) |
| Treatment-naïve (n=5) ^b | 0 (0, 1) |
| Post-chemotherapy (n=7) ^c | 1 (1, 3) |
| EGFR-mutated post-TKI (n=7) ^d | 2 (1, 4) |
| Nonsquamous histologic cell type, n (%) ^e | 18 (94.7) |
| Driver mutation-positive, n (%) ^f | 13 (68.4) |
| EGFR | 7 (36.8) |
| KRAS ^g | 6 (31.6) |
| NTRK | 1 (5.3) |
| PD-L1 tumor proportion score, n (%) ^h | |
| <1% | 13 (68.4) |
| 1-49% | 2 (10.5) |
| ≥50% | 4 (21.1) |
| Median number of target and nontarget lesions, n (min, max) | 4 (2, 10) |
| Median target lesion SOD, mm (min, max) | 61.0 (13, 218) |
| Anatomic site of TTPS, n (%) ⁱ | |
| Lung | 8 (42.1) |
| Lymph node | 5 (26.3) |
| Median time from TTPS to LN-145 infusion, d (min, max) | 39.0 (34, 84) |
| Median LN-145 dose, ×10 ⁹ cells (min, max) | 23.5 (2.8, 57.6) |

^a12 patients (63.2%) were former smokers. ^bICI-naïve patients who are treatment naïve in metastatic setting (n=5); 1 patient received neoadjuvant chemotherapy. ^cICI-naïve patients who received prior chemotherapy (n=7). ^dICI-naïve EGFR-mutated patients who received prior TKI therapy (n=7). ^e1 patient (5.3%) had squamous cell carcinoma. ^fGenes assessed include BRAF, EGFR, ALK, ROS1, KRAS, and NTRK; some patients did not have all genes assessed. ^g1 patient had a KRAS G12C mutation adjudicated between site-reported and central-laboratory data; 8 of the patients with PD-L1–negative disease were EGFR wild-type. ^h6 patients (26.3%) had other site, including bone, liver, skin/subcutaneous, buttock, post chest wall, and pleura. ⁱPer CTCAE v4.03; TEAEs include AEs that occur from the earlier of the first dose of pembrolizumab or LN-145 infusion, up to 30 days after the later of the last dose of pembrolizumab or LN-145 infusion or start of a new anticancer therapy. AE, adverse event; IL-2, interleukin 2; PD-L1, programmed death ligand-1; SOD, sum of diameters; TEAE, treatment-emergent adverse event; TKI, tyrosine kinase inhibitor; TTPS, tumor tissue procurement surgery.

Table 2. Non-hematologic TEAEs in ≥30% of Patients¹

| Preferred Term, n (%) | Cohort 3A (N=19) | |
|----------------------------|------------------|-----------|
| | Any grade | Grade 3/4 |
| Pyrexia | 15 (78.9) | 1 (5.3) |
| Hypoxia | 14 (73.7) | 11 (57.9) |
| Chills | 13 (68.4) | 0 |
| Dyspnea | 12 (63.2) | 4 (21.1) |
| Fatigue | 10 (52.6) | 3 (15.8) |
| Cough | 9 (47.4) | 0 |
| Diarrhea | 9 (47.4) | 0 |
| Hypotension | 9 (47.4) | 3 (15.8) |
| Nausea | 9 (47.4) | 1 (5.3) |
| Febrile neutropenia | 8 (42.1) | 8 (42.1) |
| Hypoalbuminemia | 8 (42.1) | 1 (5.3) |
| Sinus tachycardia | 8 (42.1) | 0 |
| Hypophosphatemia | 7 (36.8) | 6 (31.6) |
| Hypertension | 7 (36.8) | 2 (10.5) |
| Peripheral edema | 7 (36.8) | 1 (5.3) |
| Constipation | 6 (31.6) | 0 |
| Hyponatremia | 6 (31.6) | 2 (10.5) |
| Hyperglycemia | 6 (31.6) | 1 (5.3) |
| Maculopapular rash | 6 (31.6) | 0 |
| Musculoskeletal chest pain | 6 (31.6) | 0 |

Table 3. Grade 3/4 Abnormalities

| Preferred Term, n (%) |
|-----------------------|
| Neutropenia |
| Leukopenia |
| Lymphopenia |
| Thrombocytopenia |
| Anemia |

Data cutoff: 26 June 2020

- Patients were with high burden of disease
- TEAEs were common and consistent with underlying disease and safety profiles of lymphodepleting agents (see Table 3)
- No Grade 5 TEAEs

Results: Clinical Efficacy in ICI-naïve mNSCLC Responses (RECIST v1.1) Observed Independent of PD-L1 Status

Figure 2. Best Percentage Change from Baseline in Target Lesion SOD for Evaluable Patients

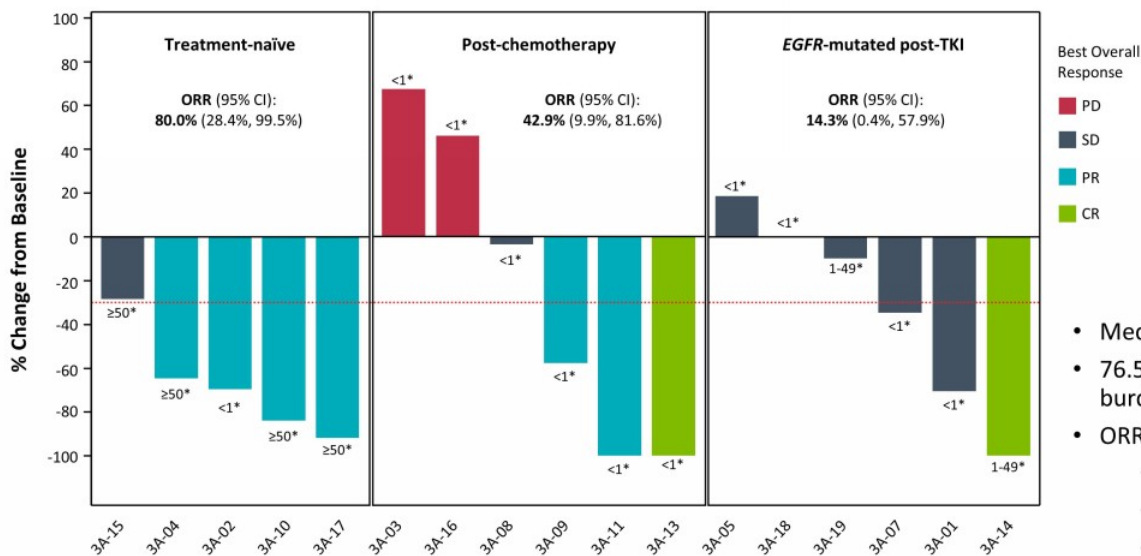


Table 4. Best Overall Response

| Best Overall Response | Cohort | |
|-----------------------|--------|-------|
| | n/N | % |
| ORR | 8/19 | 42.1% |
| DCR | 15/19 | 78.9% |
| CR | 2/19 | 10.5% |
| PR | 6/19 | 31.6% |
| SD | 7/19 | 36.8% |
| PD | 2/19 | 10.5% |
| NE | 2/19 | 10.5% |

- Median study follow-up was 18.2 months
- 76.5% of patients experienced reduced burden (**Figure 2**)
- ORR was 42.1% (**Table 4**); ORRs by p
 - Treatment-naïve: 80.0% (4/5)
 - Post-chemotherapy: 42.9% (3/7)
 - EGFR-mutated post-TKI: 14.3% (2/14)
- Treatment-naïve or post-chemo: 58.3% (7/12)

*PD-L1 status (%) as adjudicated between site-reported and central-laboratory data.

CR, complete response; DCR, disease control rate; ICI, immune checkpoint inhibitor; mNSCLC, metastatic non-small cell lung cancer; NE, non-evaluable; ORR, objective response rate; PD-L1, programmed death ligand-1; PD, progressive disease; PR, partial response; SD, stable disease; SOD, sum of diameters; TKI, tyrosine kinase inhibitor.

Results: Clinical Efficacy in ICI-naïve mNSCLC

Durable Responses Were Observed

Figure 3. Time to Response, Duration of Response, and Time on Efficacy Assessment for Confirmed Responders (PR or Better)

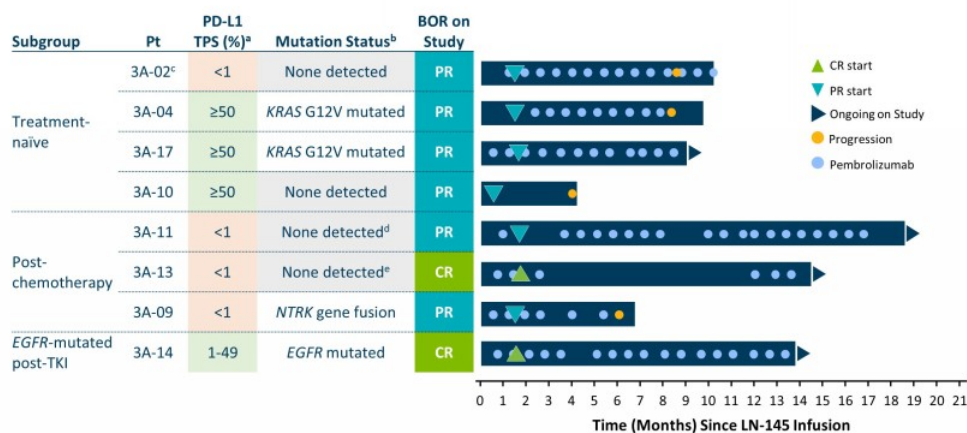
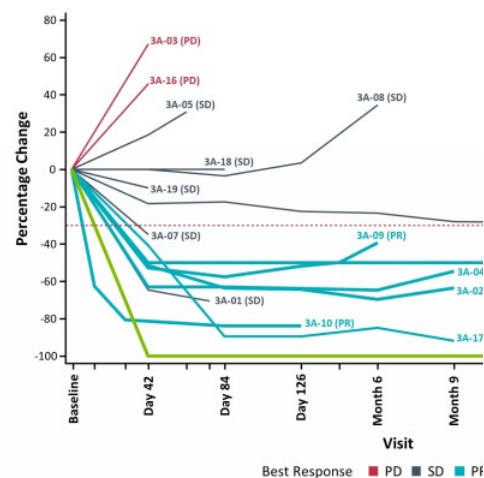


Figure 4. Percentage Change from Baseline in Target Lesion Size



- 4 responses occurred in 8 patients with *EGFR* wild-type, PD-L1–negative disease (50%) (Figure 3)
- Responses deepened over time in a subgroup of patients (Figure 4)

^aAs adjudicated between site-reported and central-laboratory data. ^bThe following genes were tested: *BRAF*, *EGFR*, *ALK*, *ROS1*, *KRAS*, and *NTRK*. ^cPatient received prior neoadjuvant chemoradiotherapy. ^d*ROS1*, *NTRK* not assessed. ^e*NTRK* not as BOR, best overall response; CR, complete response; ICI, immune checkpoint inhibitor; mNSCLC, metastatic non-small cell lung cancer; PD-L1, programmed death ligand-1; PR, partial response; SOD, sum of diameters; TKI, tyrosine kinase inhibitor tumor proportion score.

Infused TCR Clonotypes Over Time and Cell Dose

Infused TIL Persist in Peripheral Blood and Cell Dose Did Not Differ By R

Figure 5. Persistence of Infused TIL*

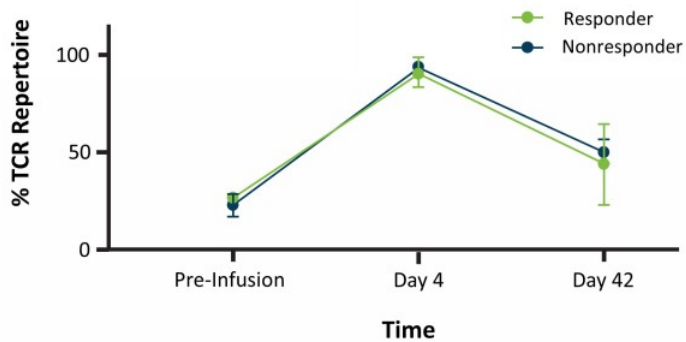
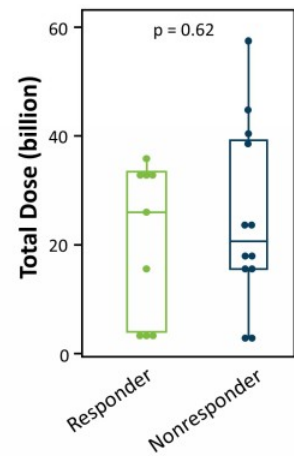


Figure 6. Total Cell Dose



- Clones from the infused TIL product persisted similarly in responders and nonresponders (**Figure 5**)

- Total cell dose infused was similar among responders and nonresponders (**Figure 6**)

*Bars represent standard error.
TCR, T-cell receptor; TIL, tumor-infiltrating lymphocyte.

Trial Conclusions

TIL Cell Therapy Activity May Be Independent of PD-L1 Status in ICI-naïv

- In patients with ICI-naïve mNSCLC, activity of LN-145 plus pembrolizumab was greater than what has previously been LN-145 monotherapy or pembrolizumab alone and was not limited by PD-L1 TPS
 - Overall, the ORR was 42.1%
 - Treatment-naïve: 80.0% (4/5)
 - Post-chemotherapy: 42.9% (3/7)
 - *EGFR*-mutated post-TKI: 14.3% (1/7)
 - Treatment-naïve or post-chemotherapy: 58.3% (7/12)
 - *EGFR* wild-type, PD-L1-negative disease: 50.0% (4/8)
 - No new safety signals were observed with pembrolizumab addition to the LN-145 regimen
- Durable and deepening responses (up to 15.4 months and ongoing) were observed and TIL clones persisted after infu
- No difference was observed in cell dose infused for responders and nonresponders
- These results support further clinical investigation of LN-145 in ICI-naïve mNSCLC and inform design of a phase 3 stud added to front-line standard of care therapy for patients with mNSCLC

Copies of this presentation obtained through QR (Quick Response) and/or text key codes are for personal use only and may not be reproduced without written permission of the authors.



ICI, immune checkpoint inhibitor; mNSCLC, metastatic non-small cell lung cancer; ORR, objective response rate; PD-L1, programmed death ligand-1; TKI, tyrosine kinase inhibitor; TPS, tumor proportion score.

Adam Schoenfeld, Memorial Sloan Kettering Cancer Center, New York, NY, USA



Corporate Overview

August 16, 2023

ADVANCING IMMUNO-ONCOLOGY

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Forward-Looking Statements

Certain matters discussed in this press release 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 press release, other than 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 the 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 identify forward-looking statements. Forward-looking statements are based on assumptions and assessments made in light of management’s experience and perception of historical 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 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-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 activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements. In addition, we could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled “Risks” in our 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 including, but not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: preliminary and interim clinical results, which may include safety results, from ongoing clinical trials or cohorts, including but not limited to our IOV-LUN-202 trial, may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain approval from the U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize our product candidates for which we obtain FDA approval; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, may support registration and subsequent approvals by the FDA, including the risk that the planned single-arm Phase 2 IOV-LUN-202 trial may not support registration; the risk that our enrollment may be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the risk that we may be required to conduct additional or 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 clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA (including from the prior pre-BLA meeting with the FDA regarding our prior meetings with the FDA regarding our NSCLC clinical trials); the risk that the FDA may not approve our BLA submission for lifileucel in metastatic disease or acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our product candidates at third-party manufacturers or our own facility may adversely affect our potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk regarding the successful integration of the recent Proleukin acquisition; the risk that the successful commercialization of our products may not generate sufficient revenue from product sales, and we may not become profitable in the near term or, if at all; unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; and other factors, including economic conditions and regulatory developments, not within our control.

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

Platform

600+

Patients Treated with Iovance TIL

90%+

Manufacturing Success Rate

22-day

Proprietary Manufacturing Process

Pipeline

1 BLA Filed

7 Active Clinical Trials

5 Tumor Types in Clinic

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

People & Assets

~\$317M*

Cash Position as of 6/30/23

60+

US and International Patents

500+

Employees

Abbreviations: BLA=Biologics License Application; BTD=Breakthrough Therapy Designation; RMAT=Regenerative Medicine Advanced Therapy Designation

*Includes net proceeds from an at-the market (ATM) equity financing facility of approximately \$260 million raised during the first quarter 2023. Cash position, including estimated net proceeds of approximately \$161 million from Iovance's public offering of 23,000,000 shares of common stock at a price of \$7.50 per share which closed July 13, 2023, is expected to fund Iovance's operating plan into the end of 2024.

■ Proleukin® Transaction Strategic Benefits

Acquisition completed May 18, 2023

- Global rights to Proleukin® (aldesleukin, human recombinant IL-2) and associated revenue
- Secure IL-2 supply chain for lifileucel regimen
- Lower clinical trial costs and future COGS
- Significant additional revenue expected with TIL commercialization

Key Figure

£167.7M

£41.7M

Financed v
existing c

Iovance Solid Tumor Pipeline Highlights

| | PRODUCT CANDIDATE | INDICATION(S) | PHASE 1 | PHASE 2 |
|---|---------------------------------|--------------------------------|--------------------------------|-----------------------|
| Advanced Melanoma (Metastatic or Unresectable) | TIL (Lifileucel/LN-144) | Post-anti-PD-1 | C-144-01, Cohorts 2 & 4 | |
| | Lifileucel + pembro | Frontline | TILVANCE-301 Phase 3 | |
| | Lifileucel + pembro | Anti-PD-1 naïve | IOV-COM-202, Cohort 1A | |
| <i>Next Generation</i> | PD-1 Inactivated TIL (IOV-4001) | Post-anti-PD-1 | IOV-GM1-201, Cohort 1 | |
| Metastatic NSCLC | LN-145 | 2L post-chemo & post-anti-PD-1 | IOV-LUN-202, Cohorts 1 & 2 | |
| | LN-145 + pembro | Anti-PD-1 naïve | IOV-COM-202, Cohort 3A | |
| | LN-145 | 2-4L incl. post-anti-PD-1 | IOV-COM-202, Cohort 3B* | |
| | LN-145 + ipi/nivo | Post-anti-PD-1 | IOV-COM-202, Cohort 3C | |
| | <i>Next Generation</i> | LN-145 Gen 3 + core biopsy | 2L post-chemo & post-anti-PD-1 | IOV-LUN-202, Cohort 3 |
| | PD-1 Inactivated TIL (IOV-4001) | 2-4L incl. post-anti-PD-1 | IOV-GM1-201, Cohort 2 | |
| Cervical | Lifileucel | Post-chemo & post-anti-PD-1 | C-145-04, Cohort 2 | |
| | LN-145 + pembro | 1L chemo and anti-PD-1 naïve | C-145-04, 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

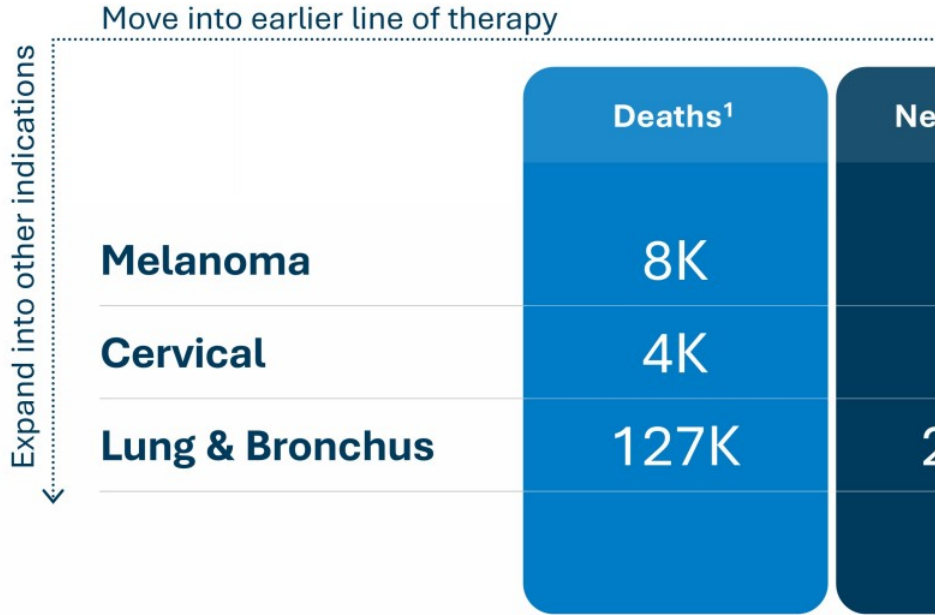
Significant Market Potential in Solid Tumors and our Key Pr

91%

of all cancer cases are solid tumors¹

1.8M

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



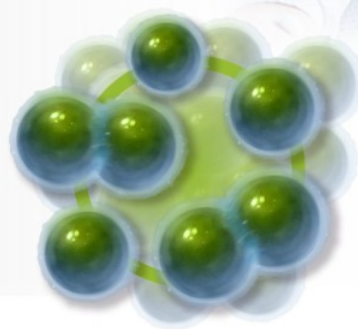
1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. <https://seer.cancer.gov> accessed May 2023

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

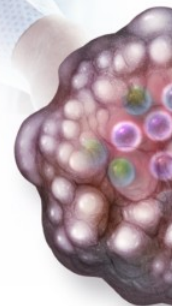
TIL – Unique Mechanism of Action

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

Lymphodepletion
& Infusion

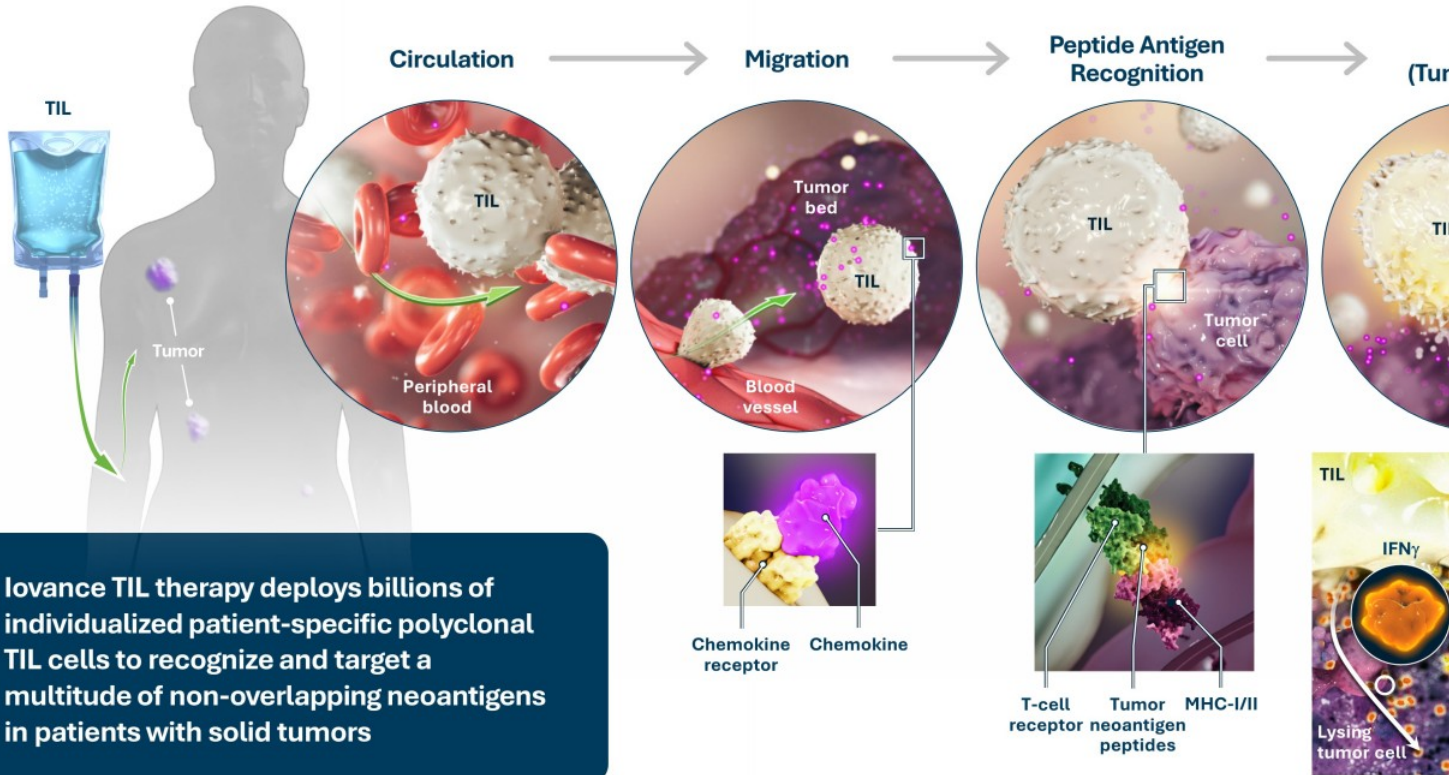


Expand & Rejuvenate
Patient-specific T Cells¹

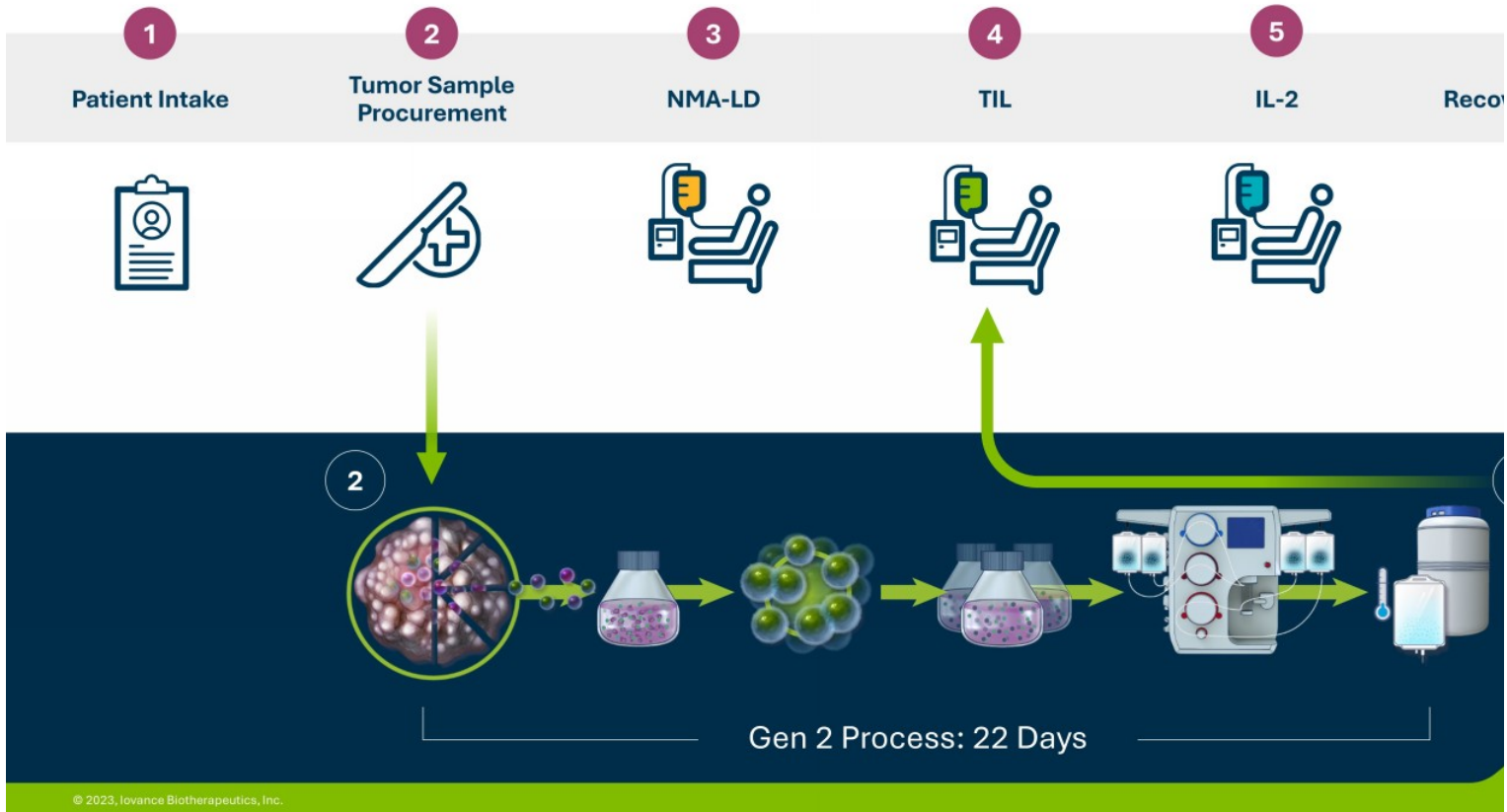


1. Simpson-Abelson et al., ESMO 2020

TIL Mechanism of Action



Iovance Streamlined 22-Day GMP Manufacturing Process



Iovance Cell Therapy Center: iCTC

Built-to-suit custom facility
in Navy Yard Philadelphia

136,000 ft², \$85M investment

LEED gold certification for
core and shell building

Honorable Mention Winner:
2022 ISPE Facility of the Year
Awards

Clinical supply initiated 3Q21

Commercial manufacturing
expected with BLA approval

Control to optimize capacity,
quality & COGS

Leading Cell Therapy Manufacturing Facility



IOVANCE
BIOTHERAPEUTICS
CELL THERAPY CENTER

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

Iovance Cell Therapy Center (iCTC): Building Annual Capacity for Thousands of Cancer Patients

Phase 1 iCTC
Today

100s

of patients/year

BLA Prep

in core suites for
commercial

4

separate flex suites
for clinical

Phase 2 iCTC
Ongoing Staffing

2,000+

patients/year

12

core suites for
commercial

4

separate flex suites
for clinical

Phase 3 iCTC
Expansion¹

5,000+

patients/year

24

core suites for
commercial

4

separate flex suites
for clinical

Phase 4 iCTC-
Additional Site

10,000

patients/year

iCTC

**Adjacent
new sites**

Automati

1. Expansion within existing shell 2. Option to build on adjacent parcel

© 2023, Iovance Biotherapeutics, Inc.

A microscopic view of cells, likely melanoma cells, rendered in a blue and purple color palette. The cells are irregular in shape and some show internal structures. The background is a dark blue gradient.

Iovance TIL Therapy in Advanced Melanoma

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Unmet Medical Need for Metastatic Melanoma Therapy

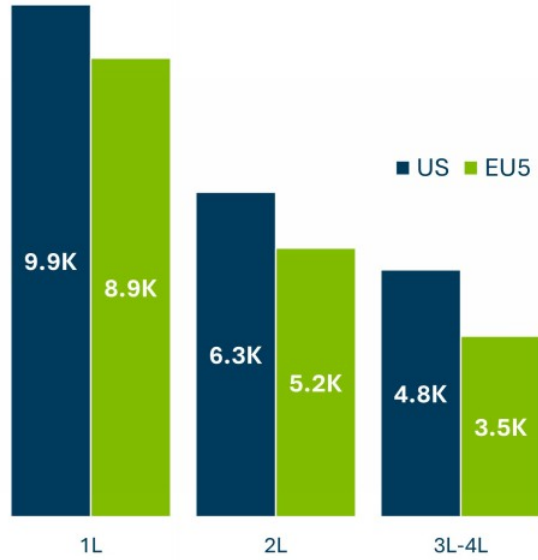
No FDA Approved Treatment Options After Progression on ICI (Anti-PD-1) Therapy and BRAF/MEK inhibitor

15k Annual new cases of advanced melanoma in U.S.¹

8k Annual deaths in U.S.²

57k Annual deaths worldwide³

Melanoma Drug-Treated Population in 2021⁴
Unresectable / Metastatic (US and EU5)



Available Ca

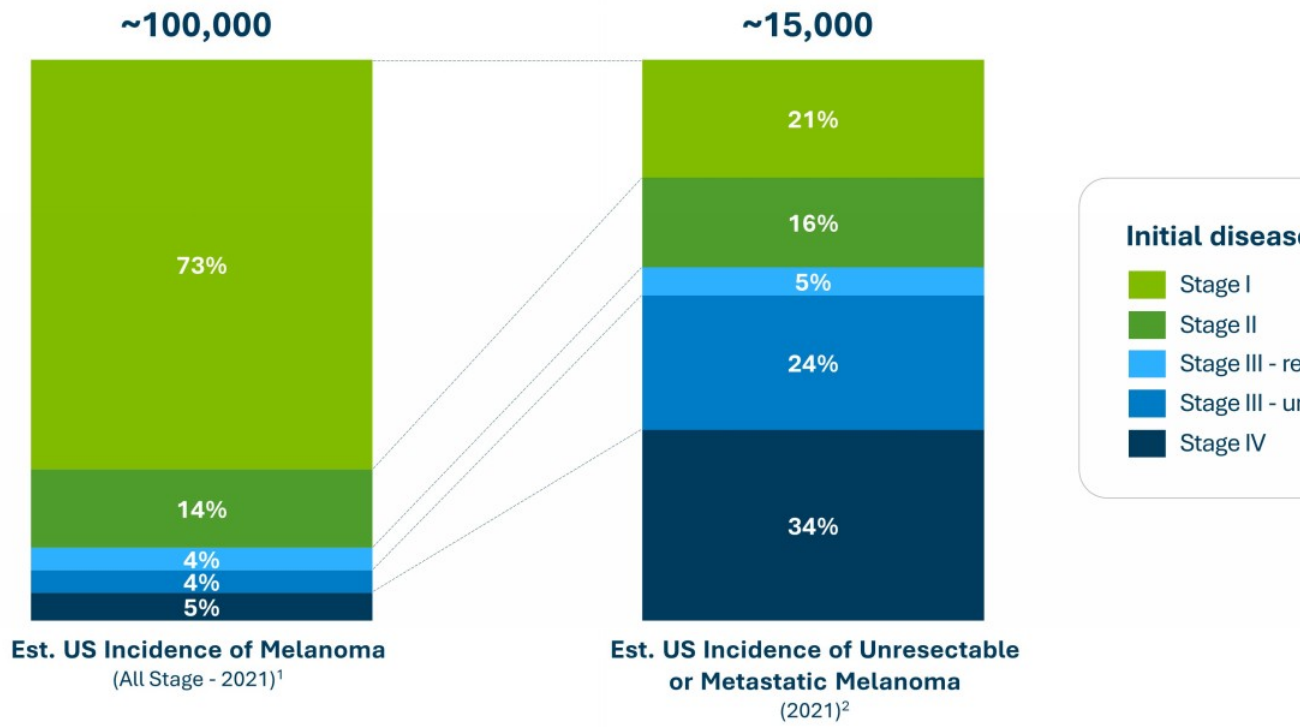
1L An Im 21

2L+ Ch OF mt

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 May 2023
3. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries, CA Cancer J Clin., May 2021
4. Clarivate DRG Disease Landscape (2021)
5. Keytruda USPI
6. Keytruda USPI (4%) and Weber et al., Lancet Oncol 2015 (ICC 10%)
7. Kirchburger et al., Eur J Cancer 2016 and Goldinger et al., J Clin Oncol 2018

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; ICI=immune checkpoint inhibitor; ORR=objective response rate; mOS=median overall survival; PD-1=programmed cell death protein-1

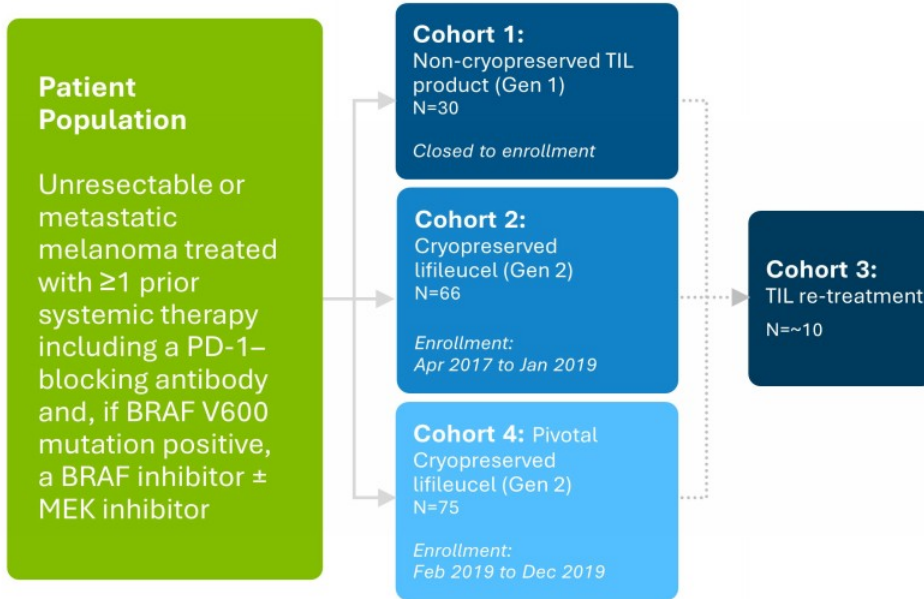
Estimated total incidence and incidence of unresectable or metastatic melanoma by initial disease stage (US)



1. Estimate of US incidence from Epiphany Health with stage III resectability status informed by market research
 2. Estimate of US incidence of unresectable or metastatic melanoma based on secondary and primary market research

C-144-01 Phase 2 Study Design

Phase 2, multicenter study to assess the efficacy and safety of autologous TIL (lifileucel) for treatment of patients with metastatic melanoma (NCT02360579)



Key Endpoints

- Primary: ORR (IRC-assessed using RECIST)
- Secondary: DOR, PFS, OS, TEAE incidence

Key Eligibility Criteria

- Tumor lesion/s for TIL generation & re-treatment
- No limit on number of prior therapies or tumor burden (including size or LDH)

Treatment Regimen (Cohorts 2 & 4)

- 22-day Gen 2 manufacturing process
- All patients received NMA-LD, a single dose of high-dose IL-2 and up to 6 doses of high-dose IL-2

Data cutoff date: July 15, 2022

Abbreviations: DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; IL-2=interleukin 2; IRC=Independent Review Committee; NMA-LD=nonmyeloablative lymphodepletion; ORR=objective response rate; OS=overall survival; PD-1=programmed cell death protein 1; RECIST=Response Evaluation Criteria in Solid Tumors; TEAE=treatment-emergent adverse events; TIL=tumor-infiltrating lymphocytes

Highlighted Prior Therapy and Baseline Disease Characteri

Cohorts 2 and 4 Heavily Pre-Treated and Mostly Similar;
Cohort 4 had Higher Disease Burden and LDH Elevation

Prior Therapy Experience (Cohorts 2+4)

- Median of 3 lines of therapy (range, 1-9)¹
- Median of 2 lines (range, 1-7) of ICI-containing therapy
- 113 (73.9%) retreated with ICI-containing therapy
- 125 (81.7%) received anti-CTLA-4
- 82 (53.6%) received anti-PD-1 + anti-CTLA-4 combination

Baseline Disease Charac

Disease burden (>3 lesio

83.9%

Cohort 4 (n=87)

65%

Cohort 2

Elevated LDH (>ULN), a n prognostic factor

64.4%

Cohort 4 (n=87)

40%

Cohort 2

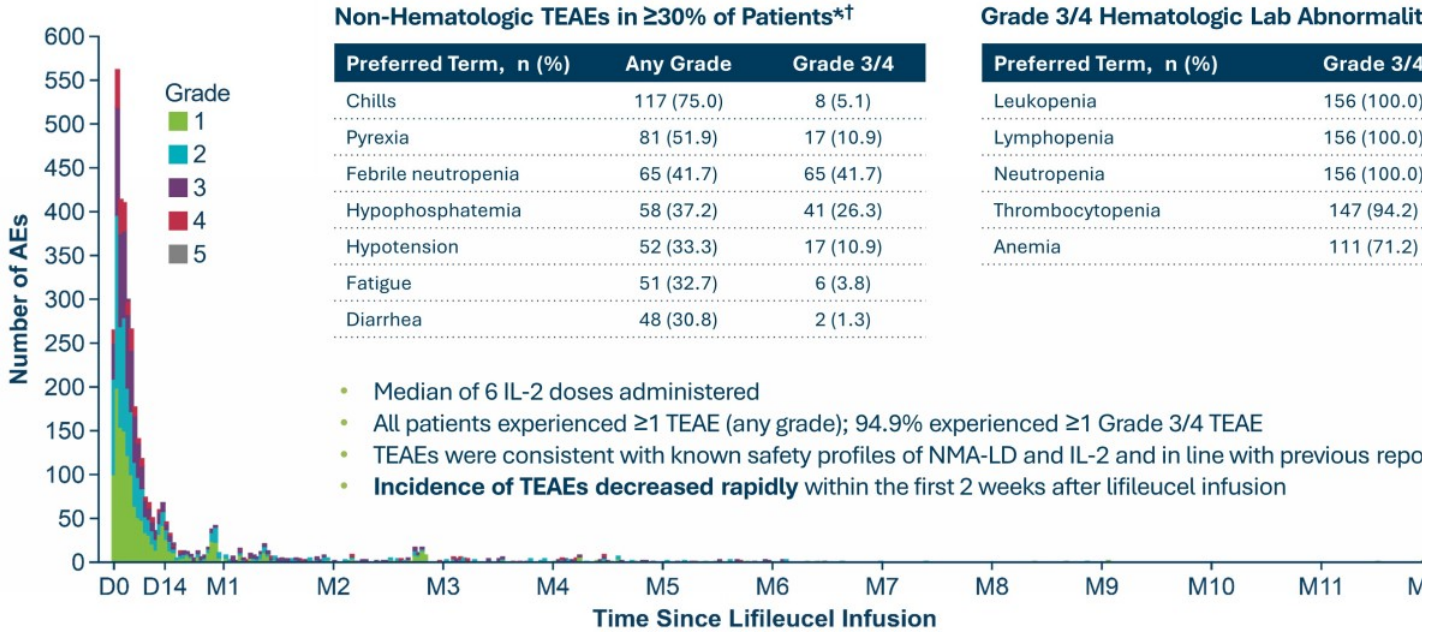
*Refer to SITC 2022 presentation for full baseline characteristics

1. All patients received prior anti-PD1 therapy

Abbreviations: CTLA-4=cytotoxic T-lymphocyte antigen 4; ICI=immune checkpoint inhibitor; LDH=lactate dehydrogenase; PD-1=programmed cell death protein 1; ULN=upper limit of normal

Safety

Transient and Manageable Nature of AEs Support the Potential Benefit of One-Time Treatment with Lifileucel



*Per CTCAE v4.03; Safety Analysis Set (N=156).

†Grade 5 TEAEs included pneumonia (n=1), acute respiratory failure (n=1), arrhythmia (n=1), and intra-abdominal hemorrhage (n=1).

All occurrences of AEs were counted if a patient experienced a new onset of the same AE at different timepoints. If multiple records were reported on the electronic case report form because of toxicity grade decrease of the same AE that had not resolved, then the event was counted once with the highest grade reported. 15 events were reported after Month 12 (Grade 1, n=7; Grade 2, n=6; Grade 3, n=1; Grade 5, n=1)

Abbreviations: AE=adverse event; D=day; IL-2=interleukin 2; M, month; NMA-LD=nonmyeloablative lymphodepletion; TEAE=treatment-emergent adverse event

Objective Response Rate (ORR) of 31.4% by IRC

91% Concordance Rate between IRC- and Investigator-assessed ORR

| | Cohort 2 (n=66) | Cohort 4 (n=87) | Cohort 2+4 (n=153) |
|-------------------------------------|--------------------|--------------------|-----------------------|
| ORR, n (%) | 23 (34.8) | 25 (28.7) | 48 (31.4) |
| (95% CI) | (23.5, 47.6) | (19.5, 39.4) | (24.1, 39.4) |
| Best overall response, n (%) | | | |
| CR | 5 (7.6) | 4 (4.6) | 9 (5.9) |
| PR | 18 (27.3) | 21 (24.1) | 39 (25.5) |
| SD | 24 (36.4) | 47 (54.0) | 71 (46.4) |
| Non-CR/Non-PD* | 1 (1.5) | 0 | 1 (0.7) |
| PD | 15 (22.7) | 12 (13.8) | 27 (17.6) |
| Nonevaluable [†] | 3 (4.5) | 3 (3.4) | 6 (3.9) |

- 33 days median resection to lifileucel
- Lifileucel manufactured within specification of patients
- Median number of cells infused was 21.1 $\times 10^9$ to 99.5 $\times 10^9$

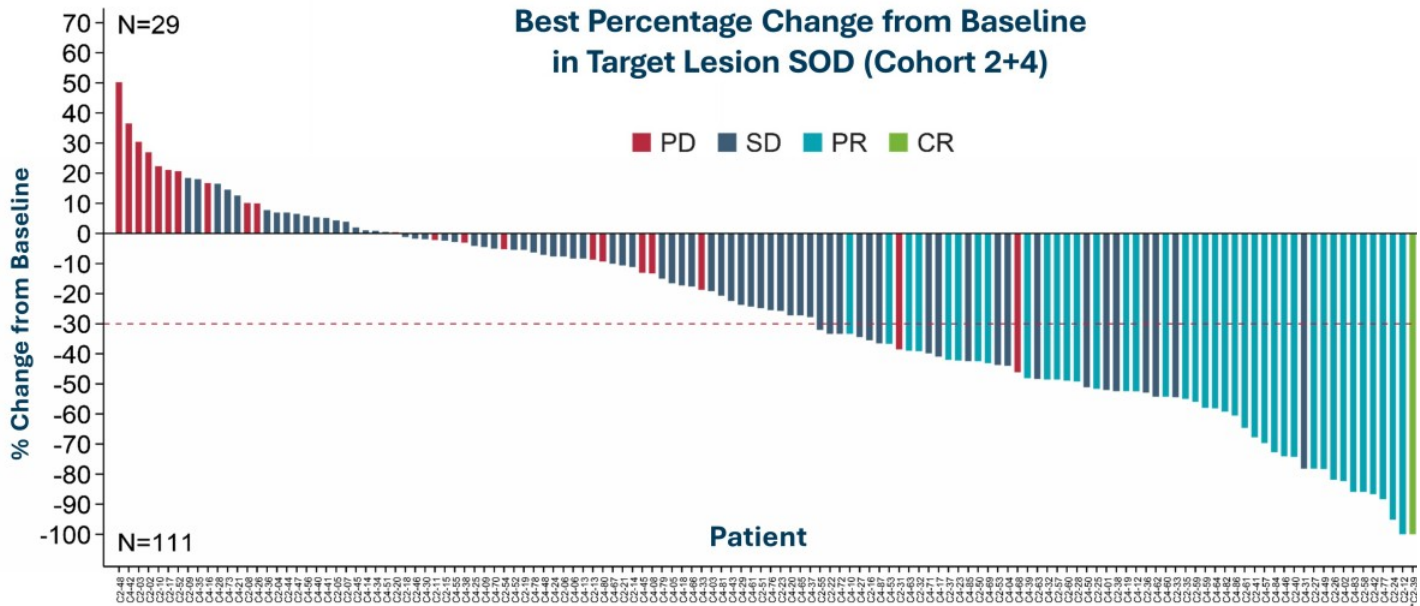
*Patient did not have acceptable target lesions and had best overall response of non-CR/non-PD per IRC assessment

[†]Six patients were nonevaluable for response (5 due to early death; 1 due to new anticancer therapy)

Abbreviations: CR,=complete response; IRC=independent review committee; ORR=objective response rate; PD=progressive disease; PR=partial response; SD=stable disease

Tumor Burden Reduction and Best Response to Lifileucel

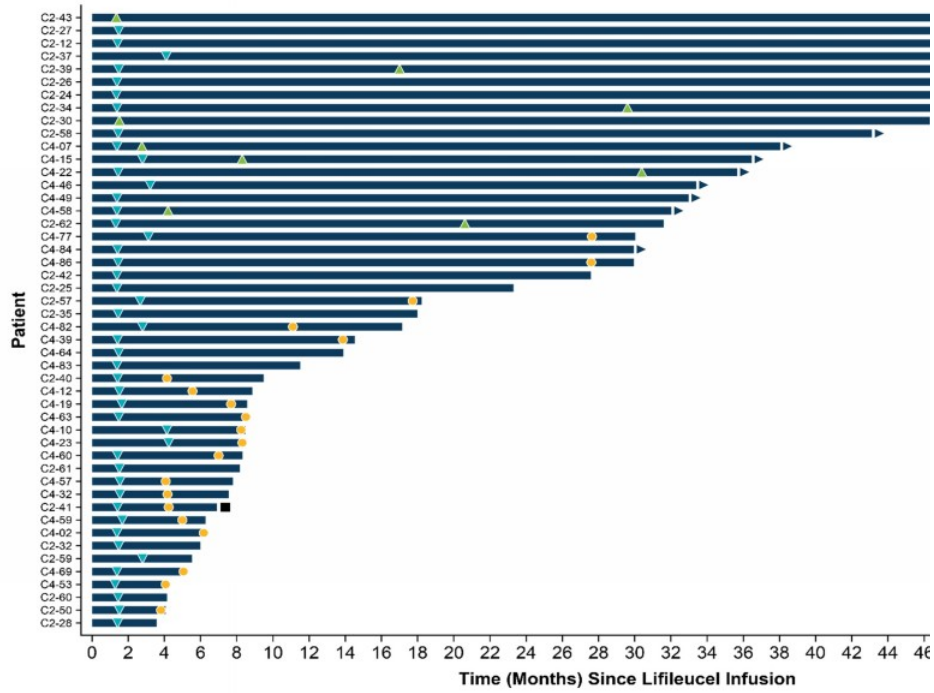
Reduction of Tumor Burden in 79.3% (111/140) of Patients



13 patients in the full analysis set are not included (9 had no post lifileucel target lesion SOD measurements, and 4 had no acceptable target lesions by IRC).
*-100% change from baseline is presented for CR assessment that includes lymph node lesions.
Abbreviations: CR=complete response; PD=progressive disease; PR=partial response; SD=stable disease; SOD=sum of diameters

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

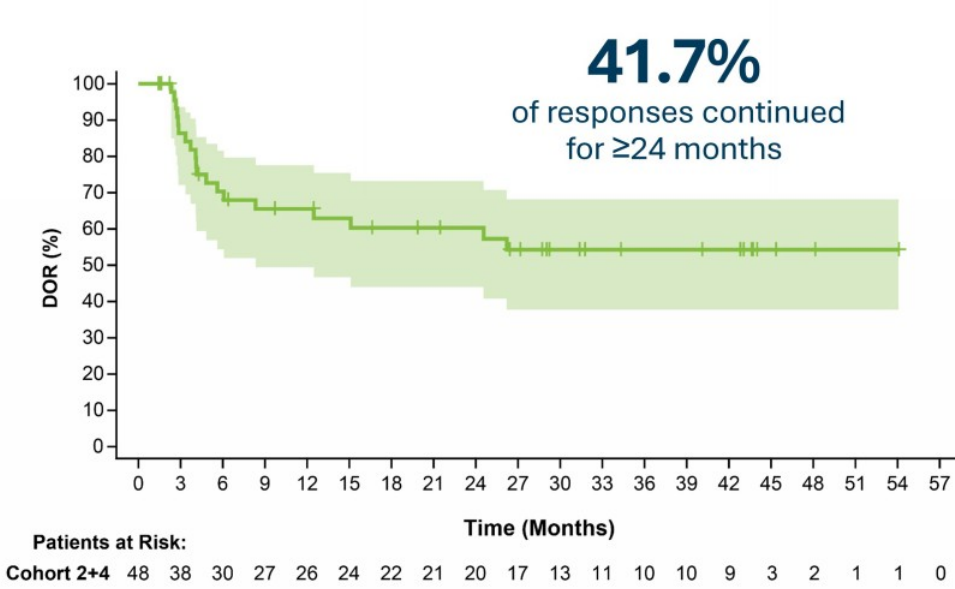
- Median time from lifileucel infusion to best response was 1.5 months
- Responses deepened over time
 - 7 patients (14.6%) initially assessed as PR were later confirmed CR
 - 4 patients (8.3%) converted to CR >1yr post-lifileucel infusion; 2 (4.2%) of 4 patients converted after 2 years
 - 10 patients (20.8%) improved from best response of SD to PR
- 35.4% of responses ongoing as of data cutoff



Abbreviations: CR=complete response; PD=progressive disease; PR=partial response; SD=stable disease

Duration of Response*

Median DOR Not Reached at Median Study Follow Up of 36.5 Months



| | Cohort 2 (n=23) | Cohort 4 (n=33) |
|---|--------------------|--------------------|
| Median follow-up, months | 45.1 | 33.5 |
| 95% CI | (44.2, 51.4) | (30.4, 36.6) |
| Median DOR[†], months | NR | 10 |
| 95% CI | (NR, NR) | (4.1, 16.0) |
| Min, max (months) | 1.4+, 54.1+ | 1.4+, 30.1+ |
| DOR ≥ 12 months, n (%) | 15 (65.2) | 11 (33.3) |
| DOR ≥ 24 months, n (%) | 11 (47.8) | 9 (27.3) |

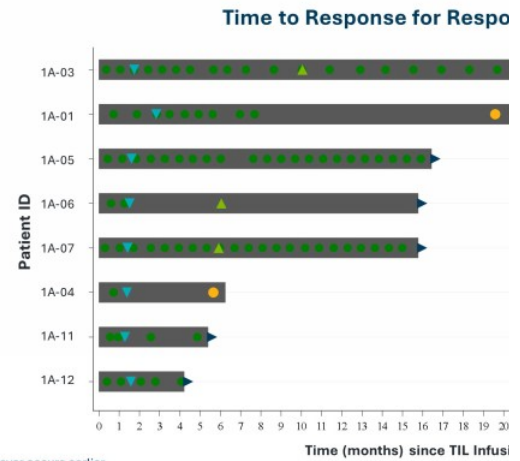
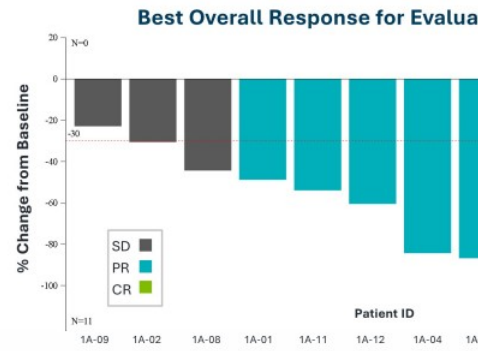
*Patients not experiencing PD or who did not die prior to the time of data cut had their event times censored at the last adequate tumor assessment. For patients who received new anticancer therapies, DOR was censored at the date of last tumor response assessment prior to the start of new anticancer therapies. For patients with PD or death immediately after ≥ 2 consecutive missing tumor assessment visits, DOR was censored at the last adequate tumor assessment prior to the missing tumor assessments.
[†]Based on Kaplan-Meier estimate
 Shaded area indicates 95% CI
 Abbreviations: DOR=duration of response; NR=not reached; PD=progressive disease

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}

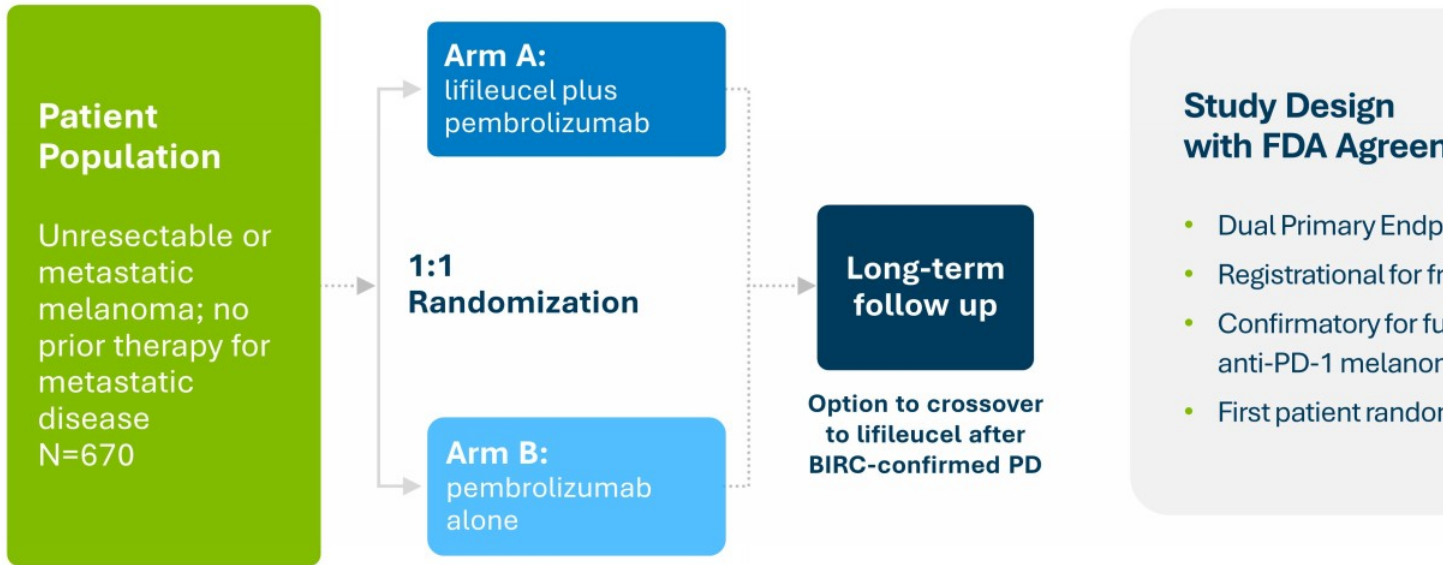
- 8 / 12 patients had a confirmed objective response per RECIST v1.1 (3 CRs & 5 PRs)
- 6 / 8 responders had ongoing response
- 5 responders had DOR >1 year
- FDA Fast Track Designation




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

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

A microscopic view of cells, likely cancer cells, showing various cellular structures and organelles. The image is overlaid with a dark blue gradient that frames the text.

Iovance TIL Therapy in Non-Small Cell Lung Cancer

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

Addressing a Substantial Unmet Need in Metastatic NSCLC

lovance TIL clinical program:

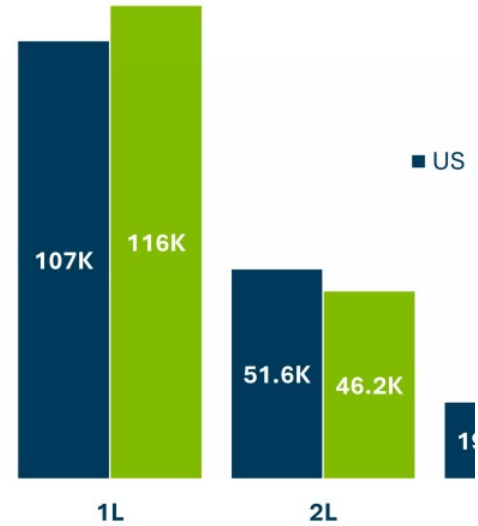
- 6 cohorts across 3 trials
- Multiple treatment regimens
- Various populations and stages of disease

127,000 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 (US and EU)



1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. <https://seer.cancer.gov> accessed May 2023

2. American Cancer Society, Lung Cancer. <https://www.cancer.org/cancer/types/lung-cancer/about.html> accessed July 2023

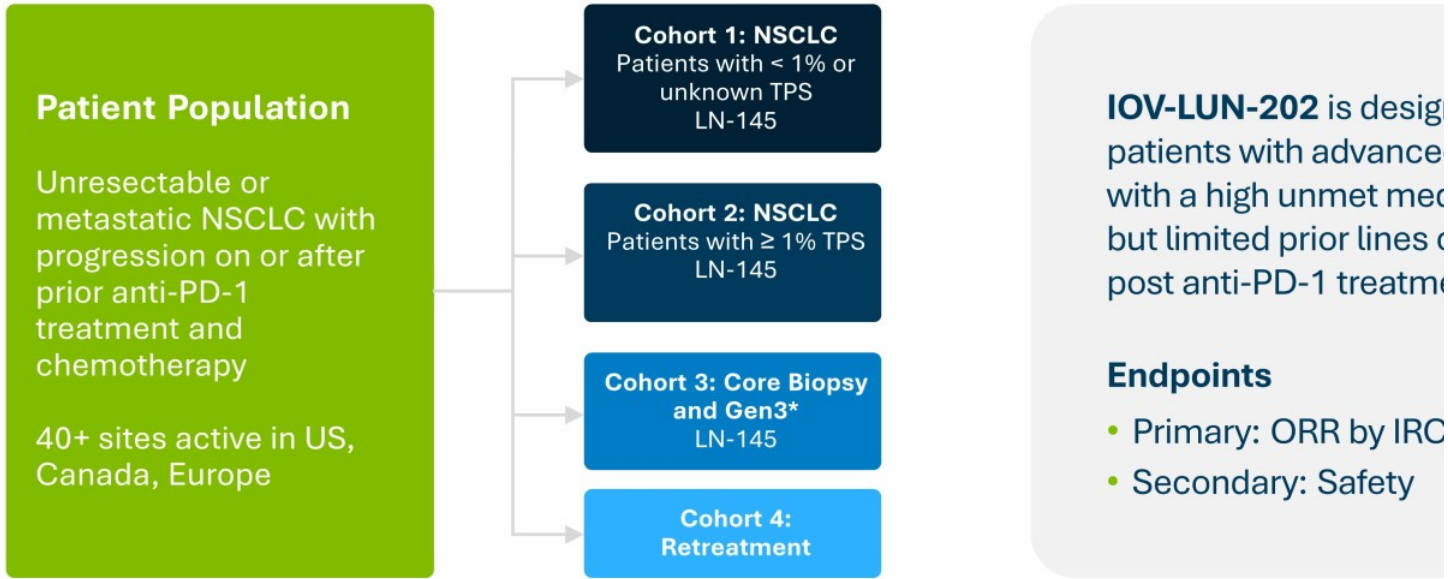
3. National Cancer Database, NSCLC survival from >1 million patients assessed. Lou Y et al. Survival trends among non-small-cell lung cancer patients over a decade: impact of initial therapy at academic centers. Cancer Med. 2018.

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)



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

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

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

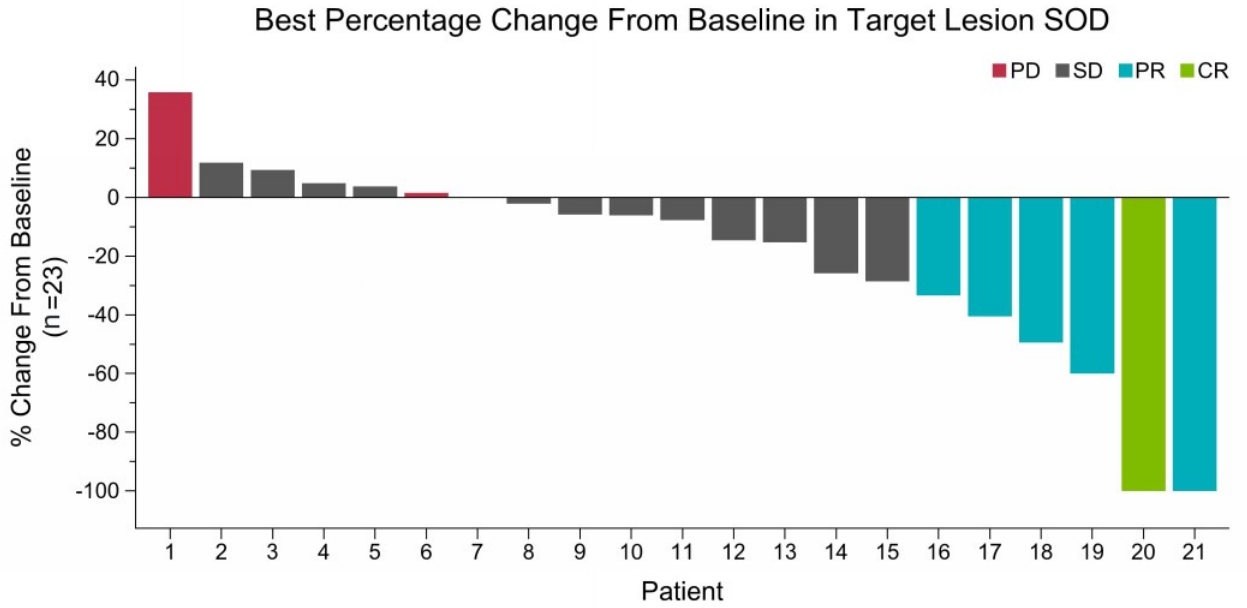
1. Data cut: July 6, 2023. Responses were assessed by investigator.

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

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

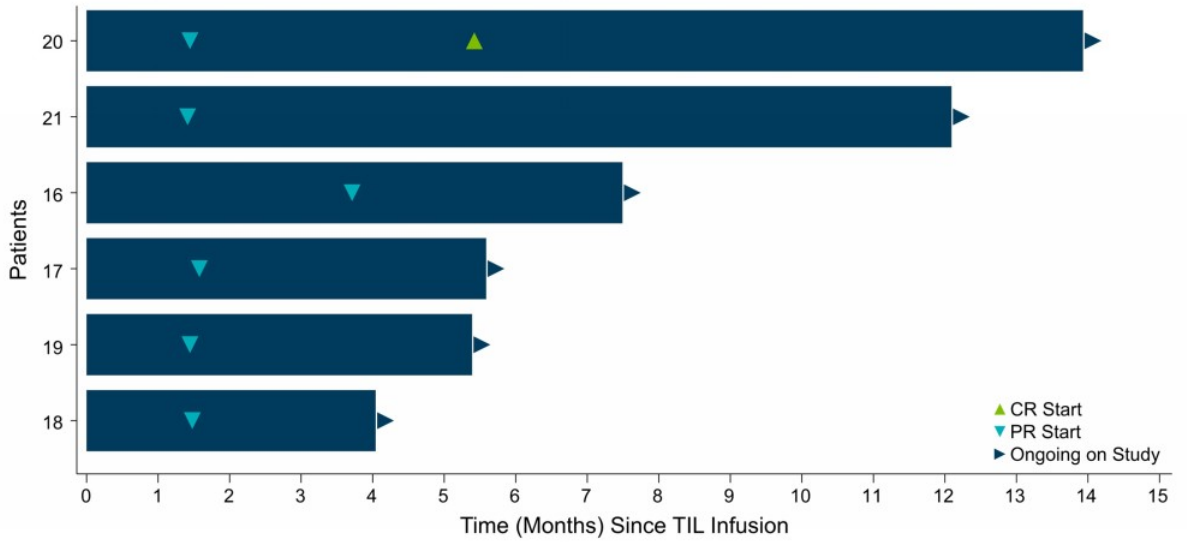


Data cut: July 6, 2023. 21 evaluable patients for response.

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 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.

Preliminary Clinical Results in ICI Naïve NSCLC

IOV-COM-202 Cohort 3A
(TIL+pembrolizumab, n=17)

| Clinical Subset | ORR, n (%) |
|--------------------------------------|------------|
| Treatment Naïve | 4/5 (80) |
| Post-Chemotherapy | 3/7 (43) |
| Treatment Naïve OR Post-Chemotherapy | 7/12 (58) |
| EGFR ^{WT} , PD-L1 Negative | 4/8 (50) |
| EGFR-Mutant, after prior EGFR-TKI | 1/5 (20) |

Abbreviations: CR, complete response; EGFR^{WT}, wild-type epidermal growth factor receptor; ICI, immune checkpoint inhibitor; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD-1, Programmed cell death protein 1; PD-L1, Programmed death-ligand 1; pembro, pembrolizumab; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; TIL, tumor infiltrating lymphocytes; TKI, tyrosine kinase inhibitor; WT, wild-type

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Clinical Activity

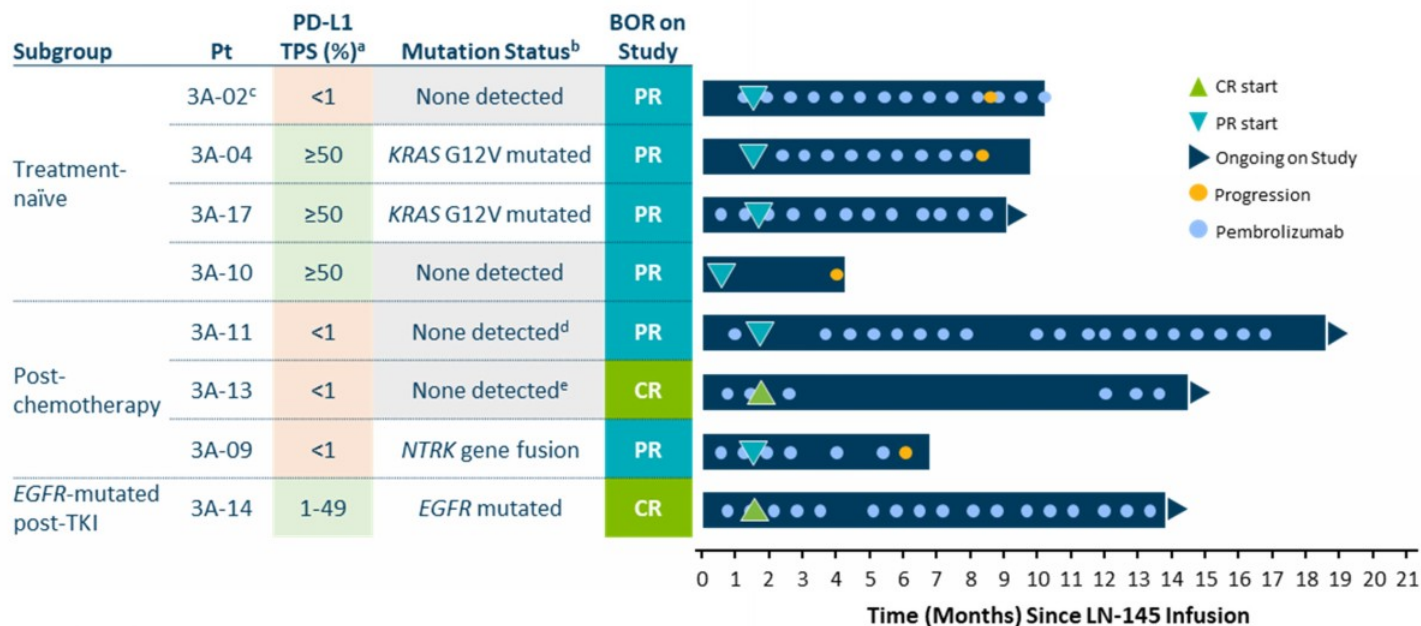
- 8/17 patients had a confirmed objective response (2 CRs and 6 PRs)
- Responses observed regardless of PD-L1 status
- Safety consistent with lovance TIL combination
- Results support the design of a subsequent phase 3 registrational trial

Regulatory Strategy

- Meet with FDA to discuss a frontline registration trial for treatment naïve EGFR^{WT} NSCLC patients:
 - Goal to improve frontline NSCLC therapy by adding TIL maintenance to standard-of-care pembrolizumab and chemotherapy, administered after completion of the initial chemo/immunotherapy
 - Seek regulatory alignment regarding the frontline NSCLC trial design for a confirmatory study for accelerated approval in post anti-PD-1

Time to Response for Confirmed Responders (n=8)

Durable Responses Observed, Including 3 Ongoing Responders with EGFR^{WT} Disease, at a Median Study Follow up of 18.2 Months



Data cut: June 26, 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.

a. As adjudicated between site-reported and central-laboratory data; b. The following genes were tested: BRAF, EGFR, ALK, ROS1, KRAS, and NTRK; c. Patient received prior neoadjuvant chemoradiotherapy; d. ROS1, NTRK not assessed; e. NTRK not assessed; f. Keytruda USPI

Abbreviations: BOR, best overall response; CR, complete response; mDOR, median duration of response; NSCLC, non-small-cell lung cancer; NSQ, nonsquamous; platinum doublet, pemetrexed and cisplatin or carboplatin; ORR, objective response rate; PD-L1, programmed death ligand 1; PR, partial response; Pt, patient; SQ, squamous; TKI, tyrosine kinase inhibitor; TPS, tumor proportion score; WT, wild-type

Moving TIL Therapy into Relevant Lines of Therapy in NSCLC

COM-202 Cohort 3A
(TIL+ pembrolizumab)

COM-202 Cohort 3C
(TIL+nivolumab/ipilimumab)

GM1-201 Cohort 2
IOV-4001 (PD1-KO TIL)

LUN-202 Cohorts 1-3
(TIL mono)

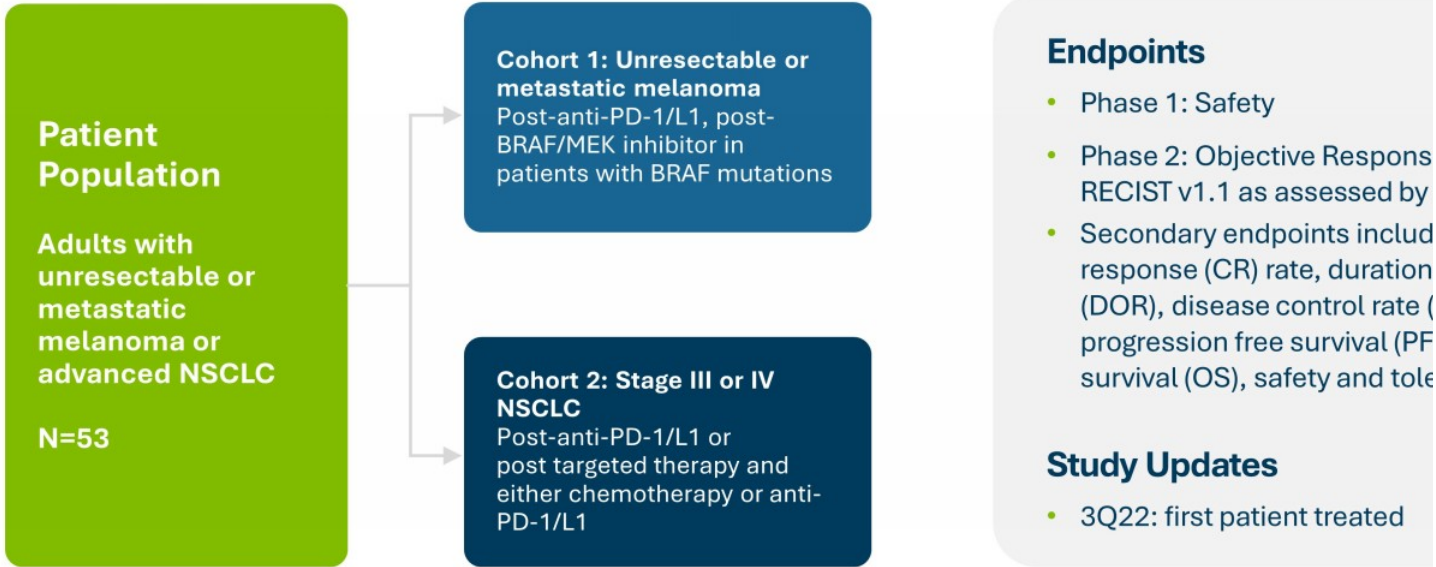
Current Standard of Care

| | | | 1L Therapy | | 2L Therapy | | 3L Therapy | | 4L Therapy | |
|---------------------|---|----------------------------|-------------------|--|-------------------|--|-------------------|--|---------------------|-------------------|
| | | | SOC | IOVA Trial | SOC | IOVA Trial | SOC | IOVA Trial | SOC | |
| Patient Populations | Advanced or metastatic NSCLC, no prior systemic therapy | Driver mutation (-) | COM-202 Cohort 3A | Anti-PD-1 Mono ORR 39-45% ¹ | COM-202 Cohort 3C | Chemo Doublet | COM-202 Cohort 3A | Docetaxel or Docetaxel + Ramucirumab ORR 9-23% ² | LUN-202 Cohorts 1-3 | GM1-201 Cohort 2* |
| | | PD-L1 ≥50% | | Anti-PD-1 + Chemo ORR 48-58% ¹ | | Docetaxel or Docetaxel + Ramucirumab ORR 9-23% ² | | LUN-202 Cohorts 1-3 | GM1-201 Cohort 2* | |
| | Driver mutation (+) | Other actionable mutations | TKI | Anti-PD-1 + Chemo ORR 48-58% ¹ | COM-202 Cohort 3A | Docetaxel or Docetaxel + Ramucirumab ORR 9-23% ² | COM-202 Cohort 3A | COM-202 Cohort 3A | GM1-201 Cohort 2* | |
| | | EGFR /ALK /ROS | 1(-3) L TKI | Chemo ORR 17-32% ³ | | | | | | |

Abbreviations: L=line; NSCLC=non-small cell lung cancer PD-1=programmed cell death protein-1; TIL=tumor infiltrating lymphocytes; TKI=tyrosine kinase inhibitor * GM1-201 Cohort 2 population is comparable to completed COM-202 Cohort 3B
1. KEYTRUDAUSPI; 2. CYRAMZA USPI; Brahmer et al., NEJM 2015; Borghaei et al., NEJM 2015; Herbst et al., Lancet 2016; Rittmeyer et al., Lancet 2017; 3. Park et al., Cancer Res Treat 2015; Yoshida et al., Lung Cancer 2017

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)



NSCLC=non-small-cell lung cancer

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Launch Preparation

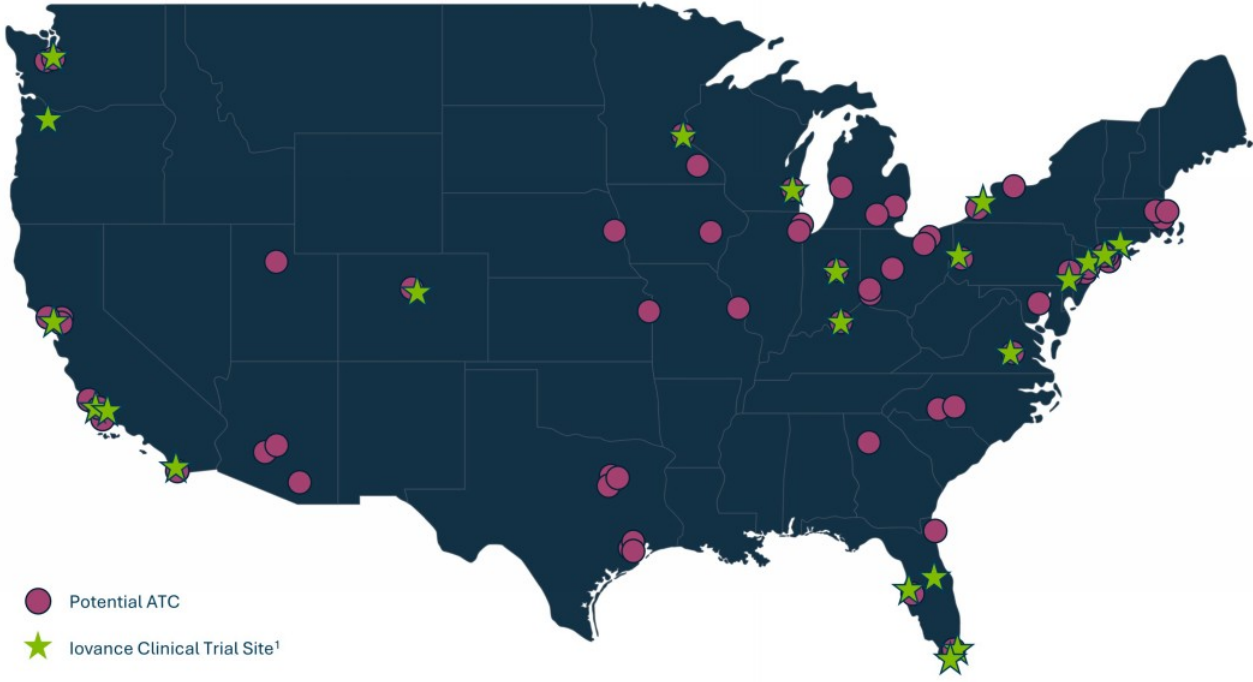
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iCTC Designed for High-Volume TIL Manufacturing and Flexibility

- Core suites: TIL commercial manufacturing
- Flexible suites: clinical supply, pipeline expansion and advanced manufacturing
- Integrated quality control, supply chain and IT systems
- 100+ employees with additional staffing into launch and beyond
- iCTC supplemented with external CDMO manufacturing capacity



Targeting Potential Authorized Treatment Centers (ATCs)



Targeting Consider

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

Drive Dei

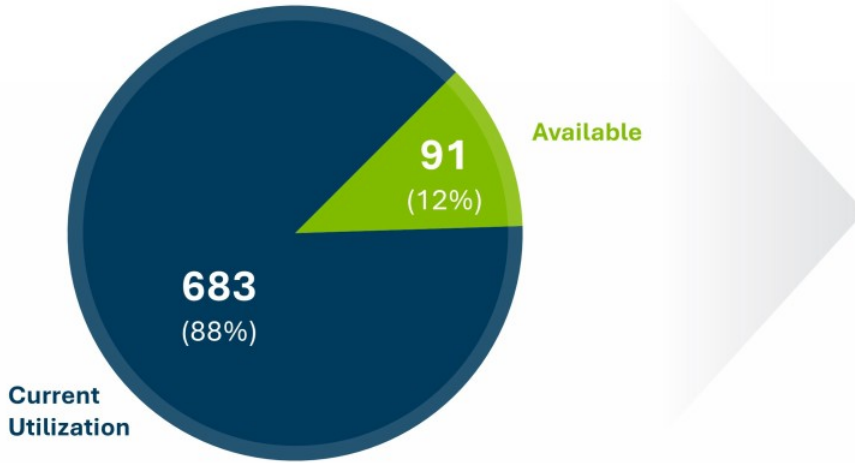
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- Commur

1. ClinicalTrials.gov
Abbreviations: NCCN=National Comprehensive Cancer Network; KOL=Key Opinion Leaders; BMT=Bone Marrow Transplant

Hospital Bed Capacity Supports Broad Lifileucel Adoption

HHS data and lovance onboarding assessments reinforce ample oncology beds

Average Beds per Target ATC¹



Hospital Bed Capacity

- HHS data reinforce sufficient overall availability at target ATCs¹
 - Average of ~ 91 available beds per target ATC
- Target ATCs report sufficient oncology availability for anticipated lifileucel demand
 - Average of ~25 available beds per target ATC per month suitable for lifileucel patients
 - Multi-disciplinary teams of clinicians and administrators invest significant resources in TIL cell therapy service lines
- Over half of target ATCs report ongoing investments that will increase inpatient capacity

Note: Oncology/cell therapy beds are a subset of the total available hospital beds

Abbreviations: ATC=Authorized Treatment Center; HHS=U.S. Department of Health and Human Services; TIL=tumor infiltrating lymphocytes

1. HHS, Daily avg bed capacity and utilization at target centers (all types of hospital beds): Jan 2022-Mar 2023, <https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capacity/cw7u>

2. lovance primary market research, 2022-2023

3. lovance secondary market research, 2023

Supporting Providers & Patients: IovanceCares™



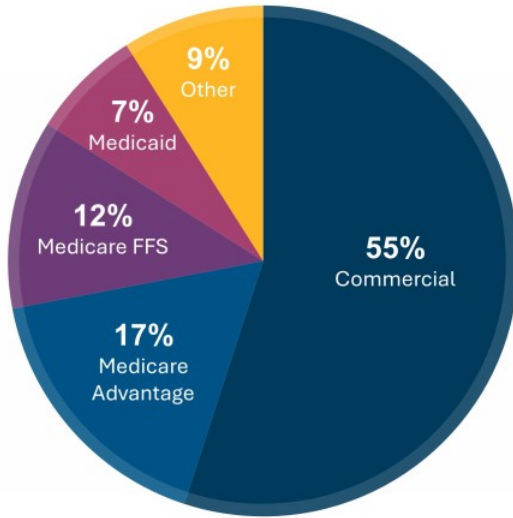
Abbreviations: COI=Chain of Identity; COC=Chain of Custody

Enabling Market Access

Lifileucel is included in established cell therapy coverage and payment methodologies

Metastatic Melanoma Payer Mix¹

All Treatment Settings and Lines of Therapy



Anticipated Access

- Engagement with Commercial and Medicare payers responsive to covered lives
- Payers reimburse hospitals established inpatient payment methodologies

Coding, Coverage and Payment

- ICD-10 PCS codes issued
- Expect payer coverage expectations similar to CARTs
- DRG-018 approved, NTAP

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. Abbreviations: FFS=Fee-For-Service; ICD-10 PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; NTAP = New Technology Add-on Payment



Other TIL Therapy Clinical Program Highlights

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Potential Market for Cervical Cancer

Addressing a Defined Unmet Need in Cervical Cancer Following Chemo and Anti-PD-1

604k New cases
WW each year¹

342k Deaths WW
each year¹

14k Diagnoses in U.S.
each year²

4k Deaths in U.S.
each year²

Available Care

ORR

Frontline:

| | |
|--|-------|
| Combination chemotherapy + bevacizumab ³ | 48% |
| Pembrolizumab + chemo + bevacizumab (PD-L1+ patients) ⁴ | 68.1% |

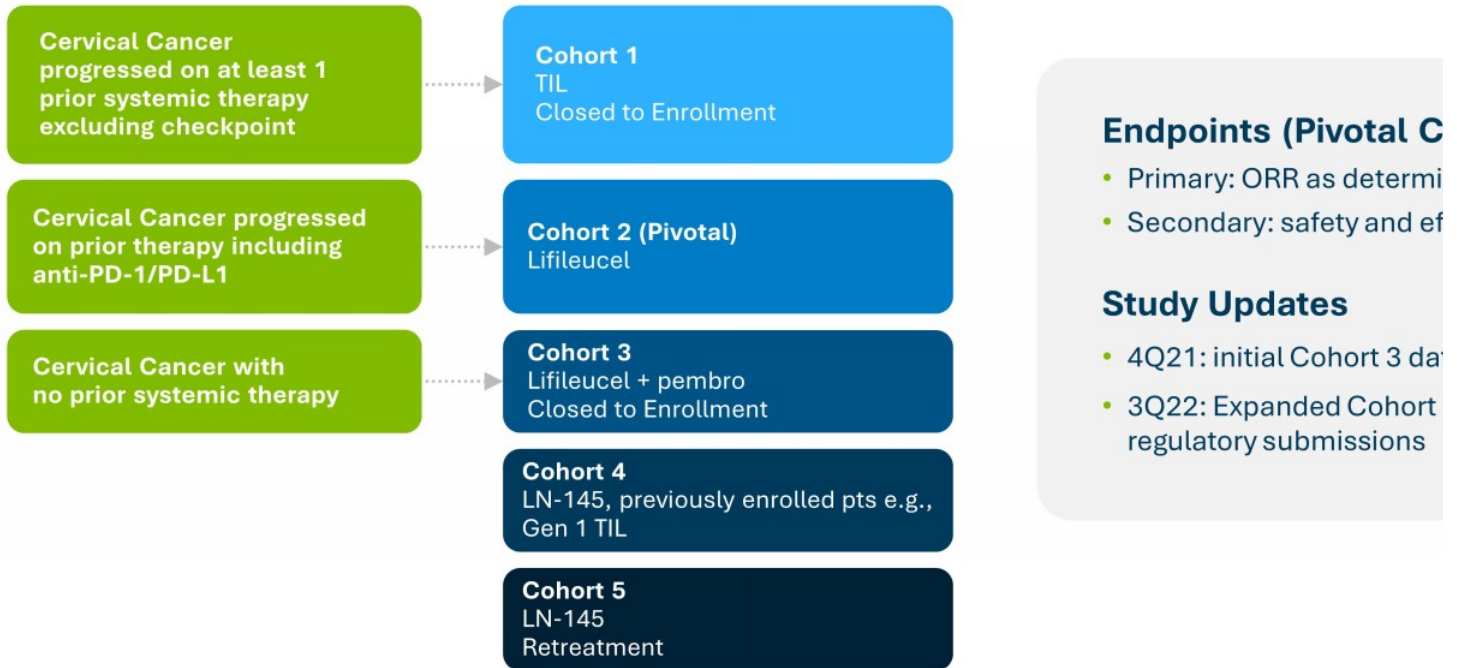
Second Line/Third Line:

| | |
|---|----------|
| Pembrolizumab post-chemo (PD-L1+ patients) ⁵ | 14.3% |
| Tisotumab vedotin-tftv post-chemo ⁶ | 24% |
| Chemotherapy in second line/third line ^{7,8} | 3.4%–15% |

1. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries, CA Cancer J Clin., May 2021; 2. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. <https://seer.cancer.gov> accessed May 2023; 3. Tewari, et al., NEJM 2014; 4. Colombo et al., NEJM 2021; 5. Keytruda USPI; 6. Coleman et al., Lancet Oncol 2021; 7. McLachlan et al., Clin Oncol 2017; 8. Miller et al., Gynecol Oncol 2008

Pivotal Phase 2 Trial of Lifileucel in Recurrent, Metastatic or Persistent Cervical Carcinoma (NCT03108495)

Regulatory Strategy Focused on Significant Unmet Need in Cervical Cancer Following Chemo and Anti-PD



1. O'Malley et al., SITC 2021



Next-Generation Research Programs

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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)

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
ena



Corporate Summary & Milestones

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Well-Capitalized in Pursuit of TIL Commercialization

June 30, 2023

(in millions)

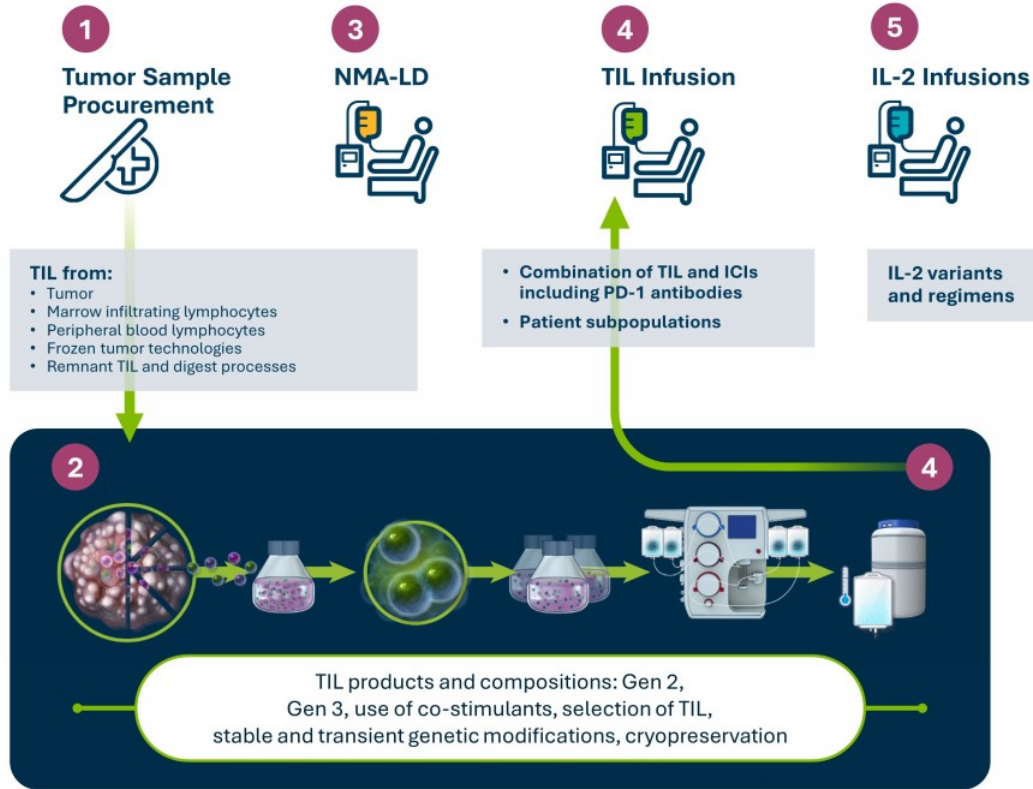
| | |
|--|----------------------|
| Cash, cash equivalents, investments, restricted cash | \$317.3 ¹ |
| Common shares outstanding | 224.7 |
| Preferred shares outstanding | 2.9 ² |
| Stock options and restricted stock units outstanding | 23.6 |

Cash runway is sufficient into the end of 2024*

**Includes estimated proceeds of lovance's public offering of 23,000,000 shares of common stock at a price of \$7.50 per share which closed July 13, 2023. The gross proceeds from the offering, before deducting the underwriting discounts and commissions and other estimated offering expenses payable by lovance, are \$172.5 million*

1. Includes Restricted Cash of \$6.4 million as of March 31, 2023.
2. Preferred shares are shown on an as-converted basis

Broad, Iovance-Owned IP Around TIL Therapy



- ✓ 60+ granted c and internatio
- ✓ Composition: for TIL produc
- ✓ Methods of tr broad range c
- ✓ Manufacturin

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 TIL, PD-1 inactivated

Potential for First Cell Therapy Approved for Solid Tumors

- BLA filed, 25 Nov 2023 PDUFA for lifileucel in advanced melanoma with Priority Review and RMAT
- TILVANCE-301 Phase 3 frontline advanced melanoma confirmatory trial with FTD
- Defined registration strategy in NSCLC and cervical cancer (BTD)

Efficient and Scalable Proprietary Manufacturing Facility

- lovance Cell Therapy Center (iCTC) in-house manufacturing
- Additional capacity with contract manufacturers
- Rapid 22-day Gen 2 manufacturing with 90%+ success rate
- >600 patients treated with lovance proprietary process

Infrastructure

- Fully in
- Experie
- function
- therapy
- Partner
- cancer
- TIL serv
- lovance
- proprie
- Proleuk

Anticipated 2023 Milestones

REGULATORY

- BLA: Complete rolling BLA submission for lifileucel in post-anti-PD-1 advanced melanoma
- BLA: Obtain FDA approval

PIPELINE

- Melanoma: enroll patients in frontline advanced melanoma Phase 3 confirmatory trial
- NSCLC: report data and continue to enroll IOV-LUN-202, IOV-COM-202, IOV-GM1-201 tr
- Cervical: enroll additional patients in registrational Cohort 2
- PD-1 inactivated TIL (IOV-4001): complete Phase 1 safety and proceed to Phase 2 of IOV
- Research: advance new products toward clinic, including additional genetically-modified

MANUFACTURING

- Execute GMP commercial readiness activities to support BLA approval and supply lifileucel

COMMERCIAL

- Prepare for and execute commercial launch
- Close transaction and successfully integrate Proleukin® business



IOVANCE

BIO THERAPEUTICS

Thank You

ADVANCING IMMUNO-ONCOLOGY

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