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): January 25, 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 January 25, 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 - January 25, 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: January 25, 2024

IOVANCE BIOTHERAPEUTICS, INC.

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


IOVANCE
BIOTHERAPEUTICS
Corporate Overview
January 25, 2024
ADVANCING IMMUNO-ONCOLOGY
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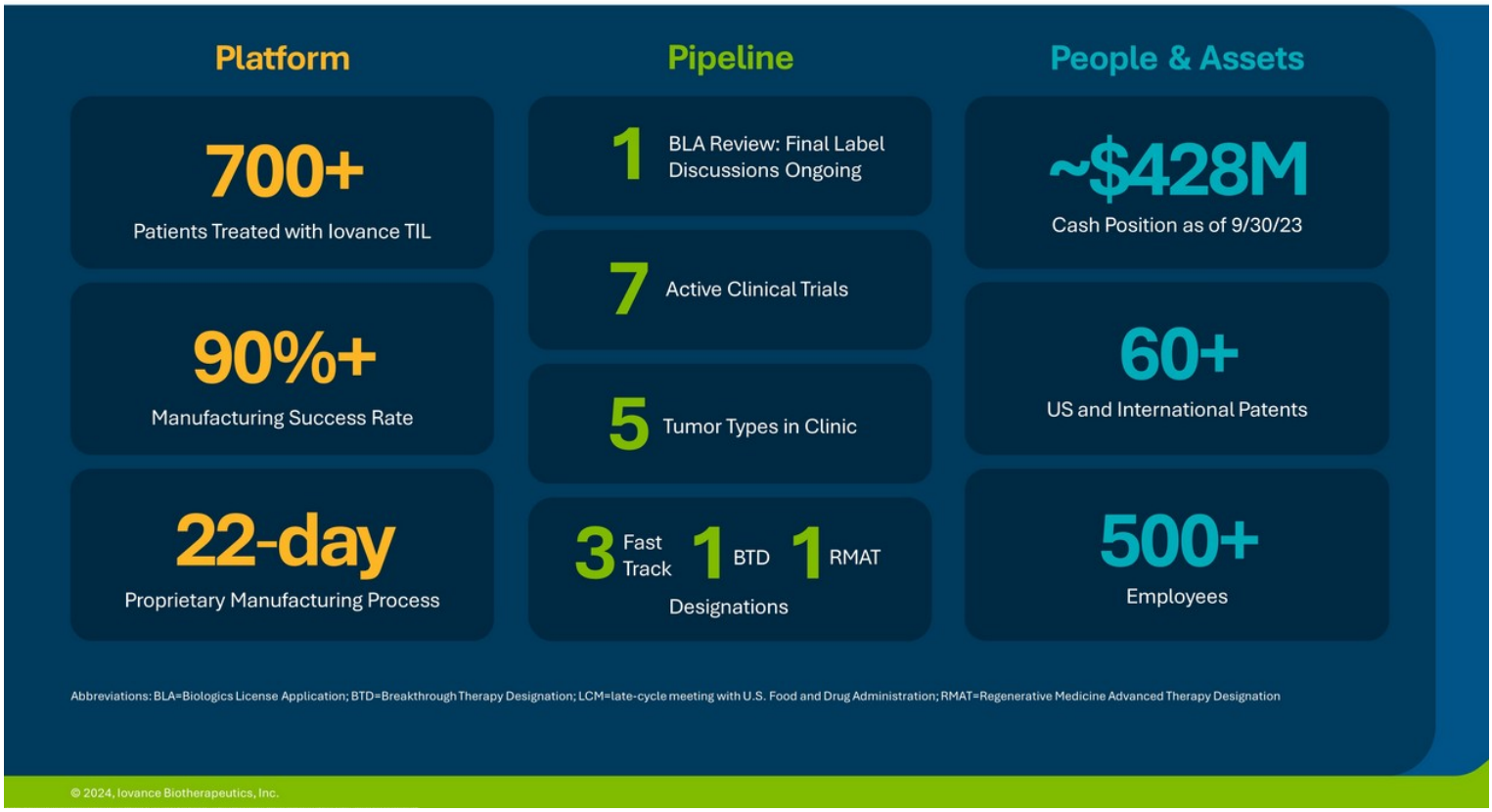
Forward-Looking Statements

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 t historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by the PSLRA. With foregoing, we may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “ “guidance,” “outlook,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes and are intended to ident statements. Forward-looking statements are based on assumptions and assessments made in light of management’s experience and perception of historica conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-look not guarantees of future performance and are subject to risks, uncertainties and other factors, many of which are outside of our control, that may cause actua activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements. Im could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Ri filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and includ limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the effects of the COVID-19 pandemic; risks related our ability to successfully develop, submit, obtain, or maintain U.S. Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”), or other regu approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtai regulatory authority approval; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authoriti registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities, including the risk that the planned single arm Phase 2 IOV-L support registration; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be r analyses 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 ou within those trials based on FDA and other regulatory agency input; the risk that the changing landscape of care for cervical cancer patients may impact our c indication; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA, EM authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA, EMA, or other regulatory authorities may differ fr interpretation of such results or communications by such regulatory authorities (including from the prior pre-BLA meeting with the FDA and/or regarding our p the FDA regarding our NSCLC clinical trials); the risk that the FDA, EMA, or other regulatory authorities may not approve or may delay approval for our BLA sub in metastatic melanoma; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved, in the U.S. and o markets; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercia of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk regarding the successful inte Proleukin acquisition; the risk that the successful development or commercialization of our products may not generate sufficient revenue from product sales become profitable in the near term, or at all; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

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



Abbreviations: BLA=Biologics License Application; BTD=Breakthrough Therapy Designation; LCM=late-cycle meeting with U.S. Food and Drug Administration; RMAT=Regenerative Medicine Advanced Therapy Designation

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	Con
	Lifileucel + pembro	Anti-PD-1 naïve	IOV-COM-202, Cohort 1A	
Next Generation	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	
Next Generation	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

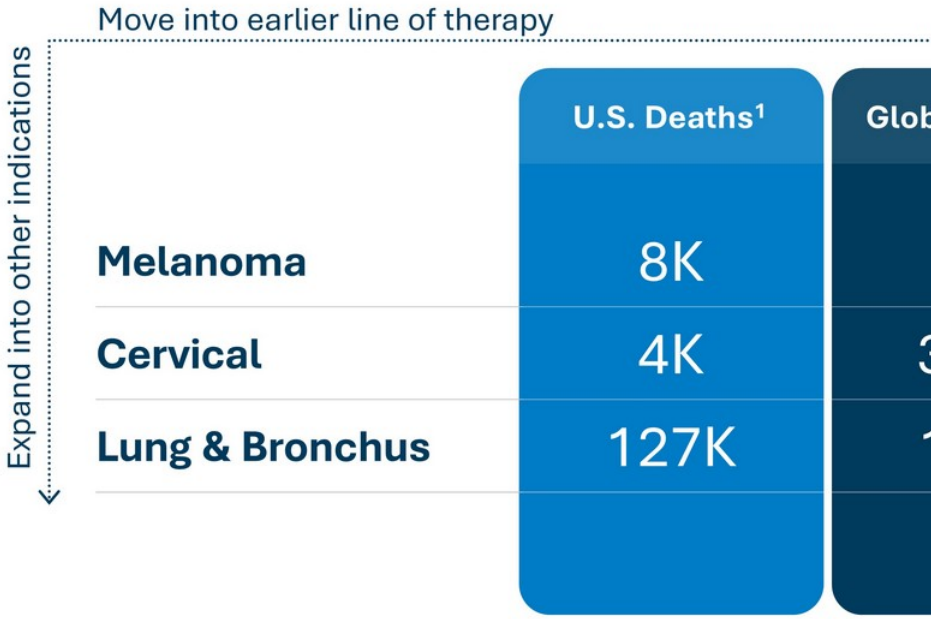
Significant Market Potential in Solid Tumors and our Key Pr

91%

of all cancer cases are solid tumors[1]

1.8M

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

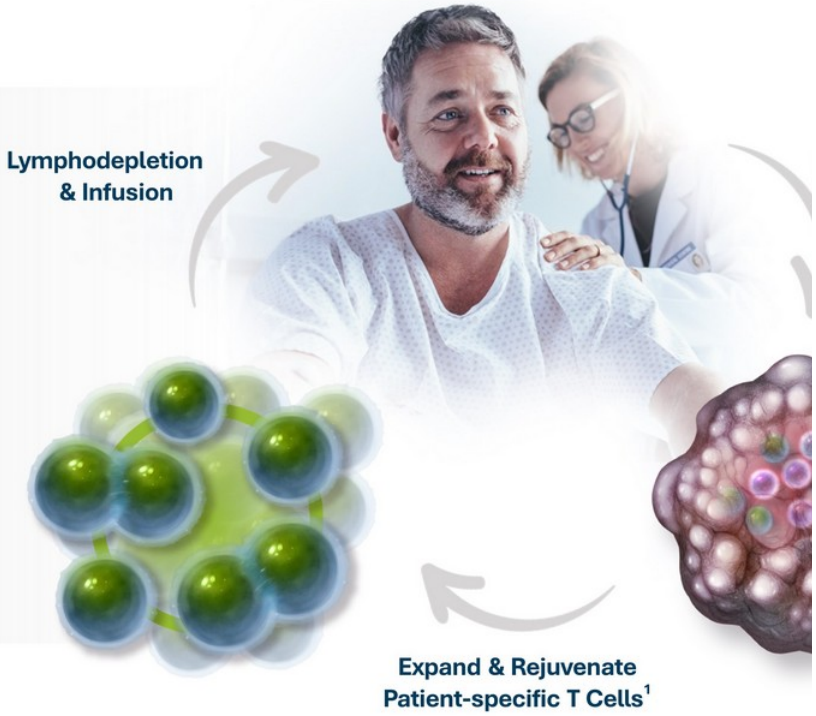


1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. https://seer.cancer.gov accessed May 2023
2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2020

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

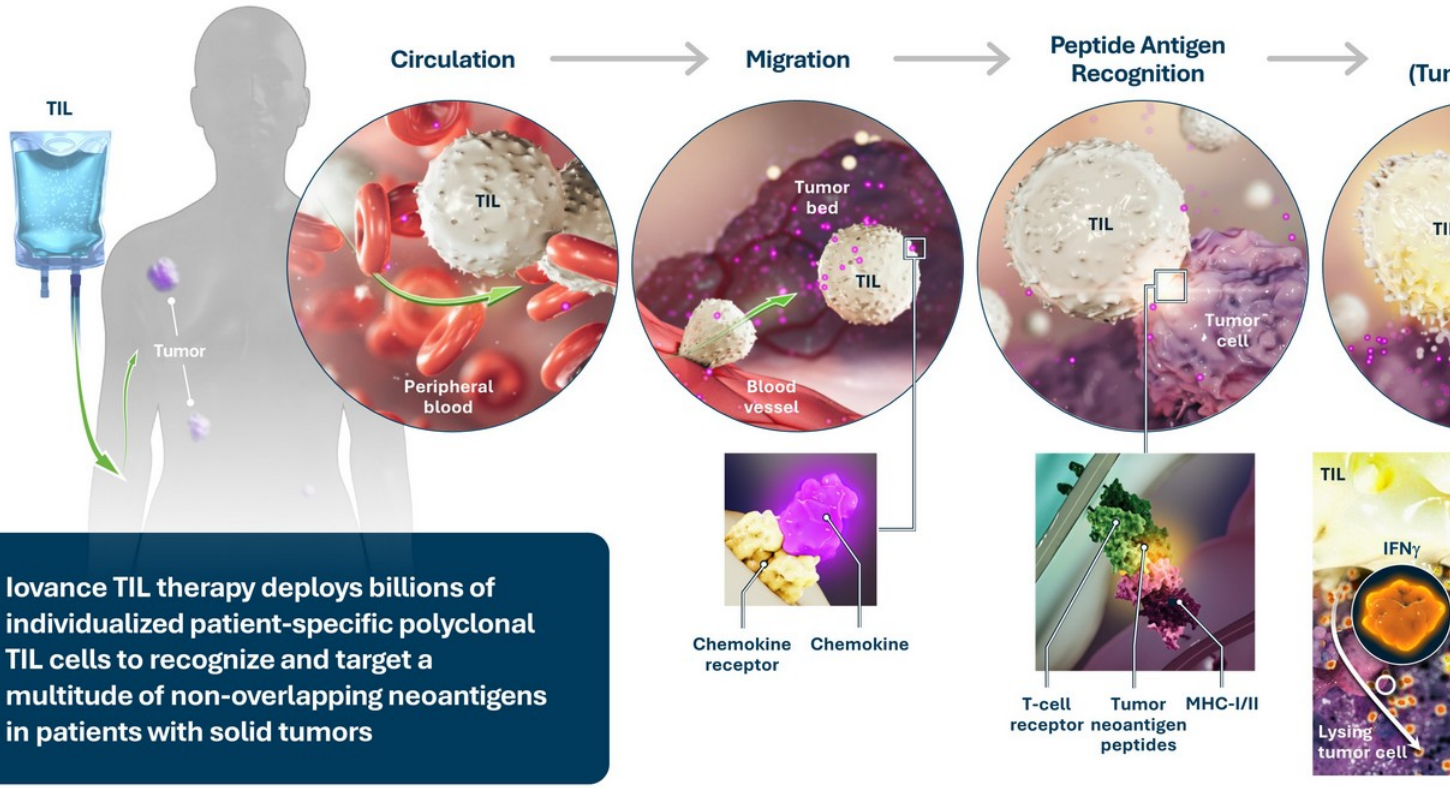
TIL – Unique Mechanism of Action

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



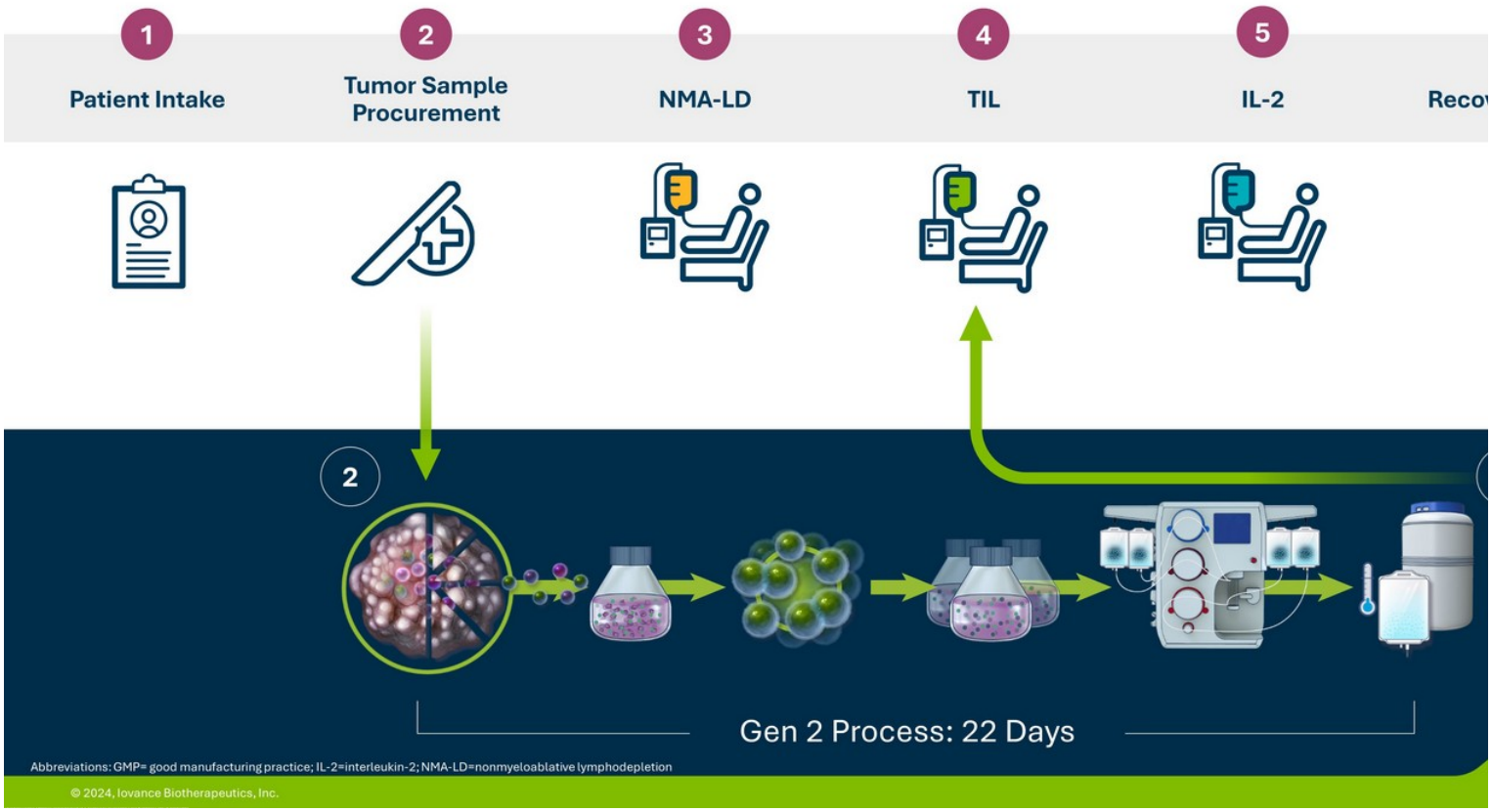
1. Simpson-Abelson et al., ESMO 2020

TIL Mechanism of Action



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

Iovance Streamlined 22-Day GMP Manufacturing Process



Iovance Cell Therapy Center: *i*CTC

Built-to-suit custom facility in Navy Yard Philadelphia

136,000 ft^2, $85M investment

LEED gold certification for core and shell building

Clinical supply initiated 3Q21

Successfully completed FDA Pre-License Inspection in 2023

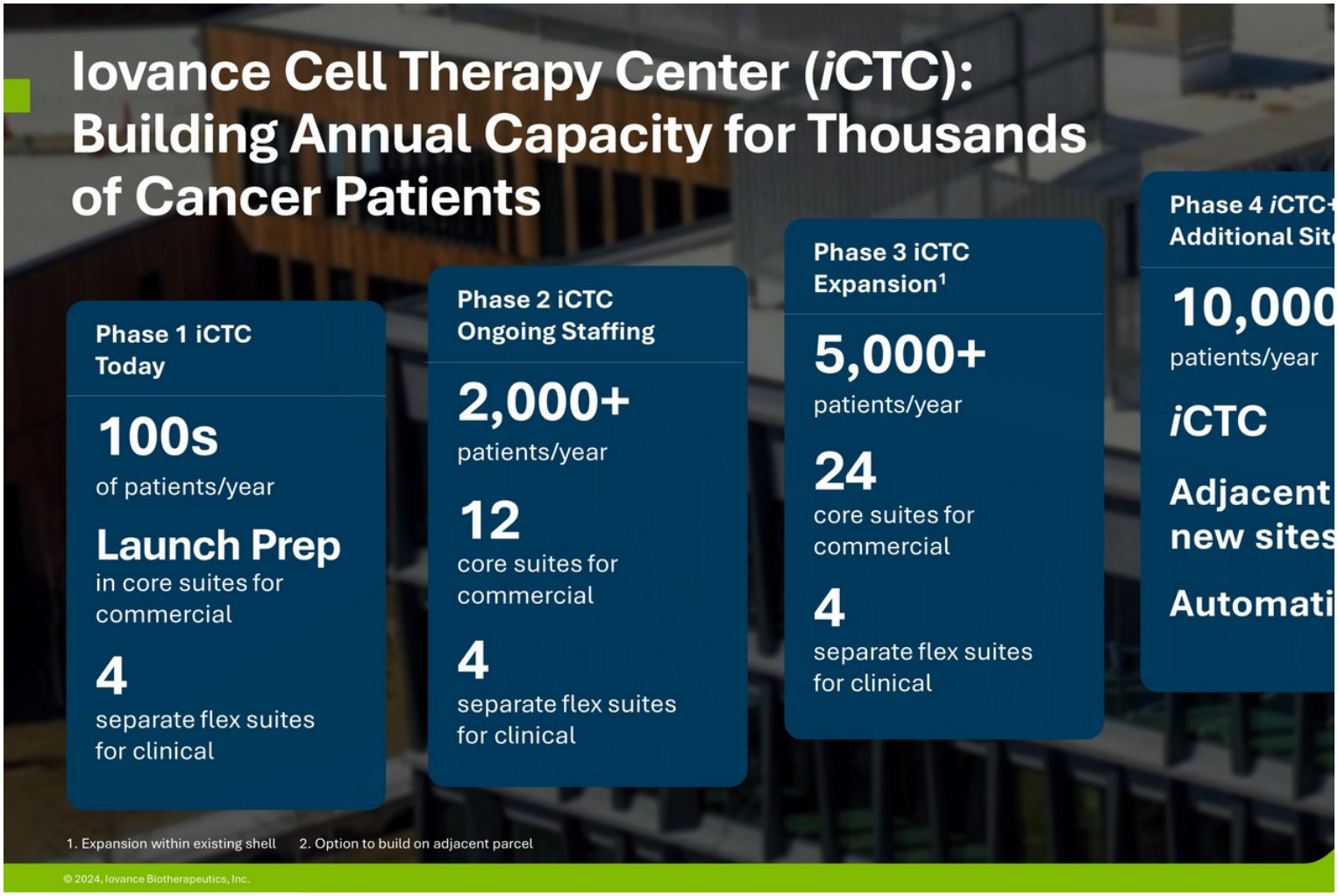
Commercial manufacturing expected with BLA approval

Control to optimize capacity, quality & COGS

Leading Cell Therapy Manufacturing Faci

IOVANCE BIOTHERAPEUTICS
CELL THERAPY CENTER

FOYA 2
ISPE Facility of the Year Awa
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
Launch 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 Expansion[1]
5,000+
patients/year
24
core suites for commercial
4
separate flex suites for clinical
Phase 4 iCTC+ Additional Sit
10,000
patients/year
iCTC
Adjacent
new sites
Automati
1. Expansion within existing shell
2. Option to build on adjacent parcel
© 2024, Iovance Biotherapeutics, Inc.

Iovance TIL Therapy in Advanced Melanoma

U.S. Unmet Medical Need for Metastatic Melanoma Therap

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

15k

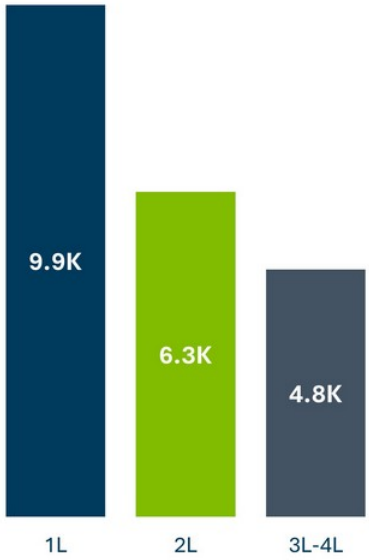
Annual new cases of advanced melanoma in U.S.[1]

8k

Annual deaths in U.S.[2]

Melanoma Drug-Treated Population in 2021[3]

Unresectable / Metastatic (US)



Available Ca

1L An Im **21** BR inh BR

2L+ Ch **OR** **mO**

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. Clarivate DRG Disease Landscape (2021)
4. Keytruda USPI
5. Keytruda USPI (4%) and Weber et al., Lancet Oncol 2015 (ICC 10%)
6. Kirchburger et al., Eur J Cancer 2016 and Goldinger et al., J Clin Oncol 2018

Abbreviations: 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

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

Opportunity to double addressable patient population with ex-U.S. expansion

57k

Annual deaths worldwide[1]

15k

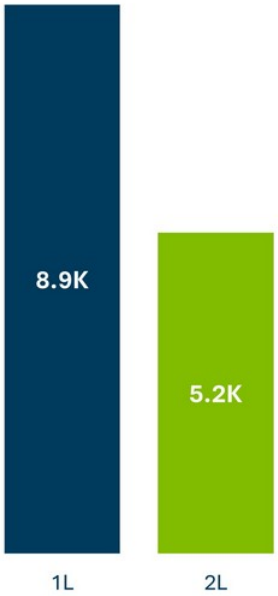
Annual deaths in ex-U.S. target markets[1]

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 P

Unresectable / Metas



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;

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)

Identi
Eligibilit
Treatme
Cohor
and

Patient Population

Unresectable or metastatic melanoma treated with ≥1 prior systemic therapy including a PD-1–blocking antibody and, if BRAF V600 mutation positive, a BRAF inhibitor ± MEK inhibitor

Cohort 1: Non-cryopreserved TIL product (Gen 1)
N=30

Closed to enrollment

Cohort 2: Cryopreserved lifileucel (Gen 2)
N=66

Enrollment: Apr 2017 to Jan 2019

Cohort 4: Pivotal Cryopreserved lifileucel (Gen 2)
N=75

Enrollment: Feb 2019 to Dec 2019

Cohort 3: TIL re-treatment
N=~10

Key Endpoints

- Primary: ORR (IRC-assessed using RE
- Secondary: DOR, PFS, OS, TEAE incid

Key Eligibility Criteria

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

Treatment Regimen (Cohorts

- 22-day Gen 2 manufacturing process
- All patients received NMA-LD, a single 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)

6
Coh

Elevated LDH (>ULN), a r prognostic factor

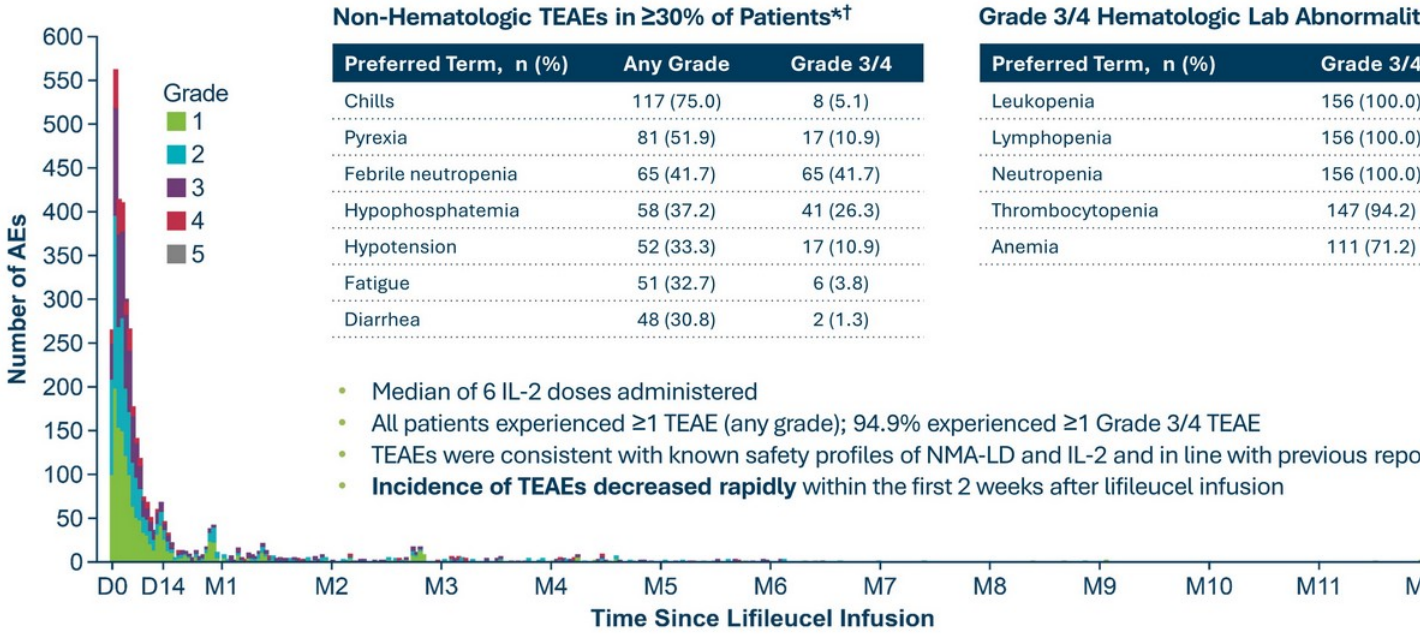
64.4%
Cohort 4 (n=87)

4
Coh

*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 Lifileuc



Non-Hematologic TEAEs in ≥30% of Patients*†

Preferred Term, n (%)	Any Grade	Grade 3/4
Chills	117 (75.0)	8 (5.1)
Pyrexia	81 (51.9)	17 (10.9)
Febrile neutropenia	65 (41.7)	65 (41.7)
Hypophosphatemia	58 (37.2)	41 (26.3)
Hypotension	52 (33.3)	17 (10.9)
Fatigue	51 (32.7)	6 (3.8)
Diarrhea	48 (30.8)	2 (1.3)

Grade 3/4 Hematologic Lab Abnormalit

Preferred Term, n (%)	Grade 3/4
Leukopenia	156 (100.0)
Lymphopenia	156 (100.0)
Neutropenia	156 (100.0)
Thrombocytopenia	147 (94.2)
Anemia	111 (71.2)

- Median of 6 IL-2 doses administered
- All patients experienced ≥1 TEAE (any grade); 94.9% experienced ≥1 Grade 3/4 TEAE
- TEAEs were consistent with known safety profiles of NMA-LD and IL-2 and in line with previous repo
- **Incidence of TEAEs decreased rapidly** within the first 2 weeks after lifileucel infusion

*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

SITC 2022 C-144-01 COHORTS 2 + 4 POOLED ANALYSIS ASSESSED BY IRC USING RECIST 1.1

Objective Response Rate (ORR) of 31.4% by IRC

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

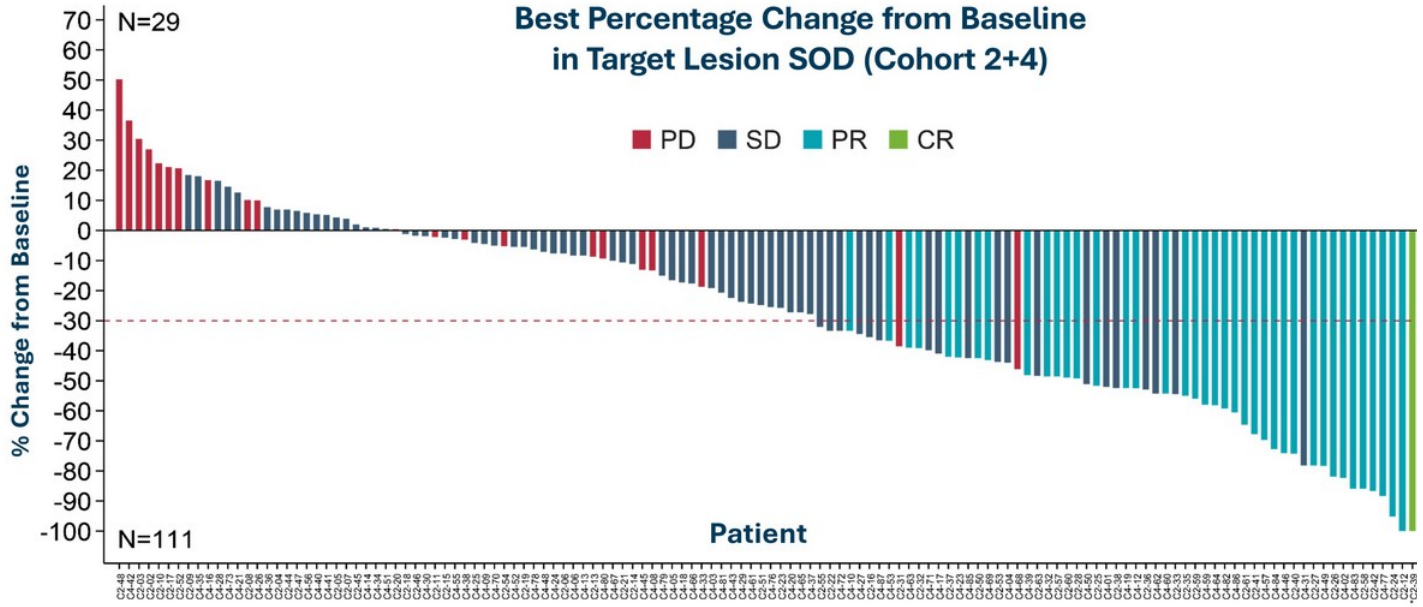
	Cohort 2 (n=66)	Cohort 4 (n=87)	Cohort 2+4 (n=153)
ORR, n (%)	**23 (34.8)**	**25 (28.7)**	**48 (31.4)**
(95% CI)	(23.5, 47.6)	(19.5, 39.4)	(24.1, 39.4)
Best overall response, n (%)			
CR	5 (7.6)	4 (4.6)	9 (5.9)
PR	18 (27.3)	21 (24.1)	39 (25.5)
SD	24 (36.4)	47 (54.0)	71 (46.4)
Non-CR/Non-PD*	1 (1.5)	0	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 lifile
- Lifileucel manuf
  within specificat
  of patients
- Median number
  infused was 21.1
  1.2×10^9 to 99.5

*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

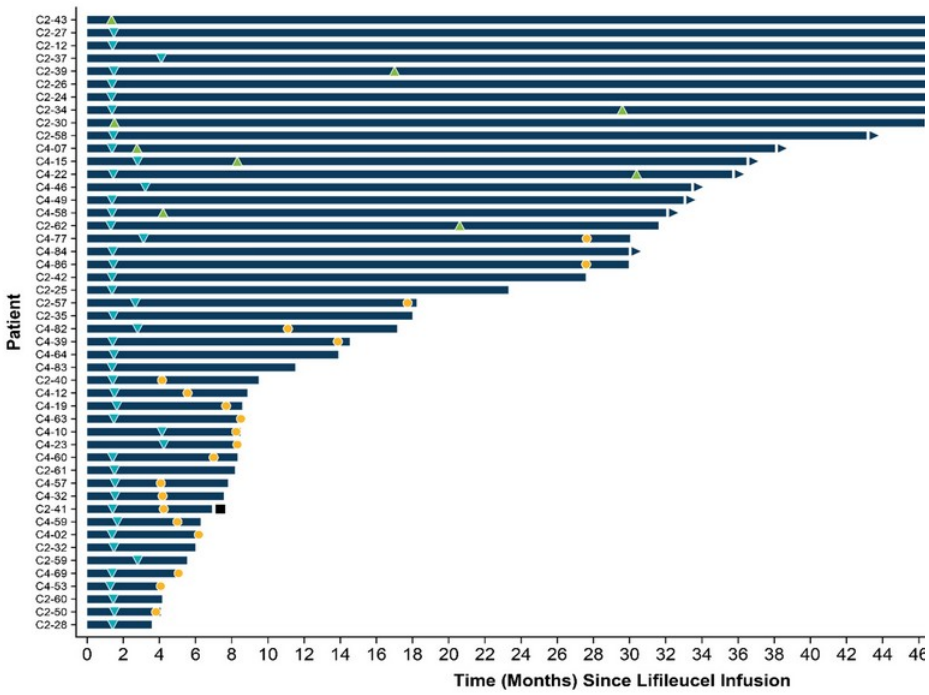
Reduction of Tumor Burden in 79.3% (111/140) of Patients



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 Effic Assessment for Confirmed Responders (PR or Better)

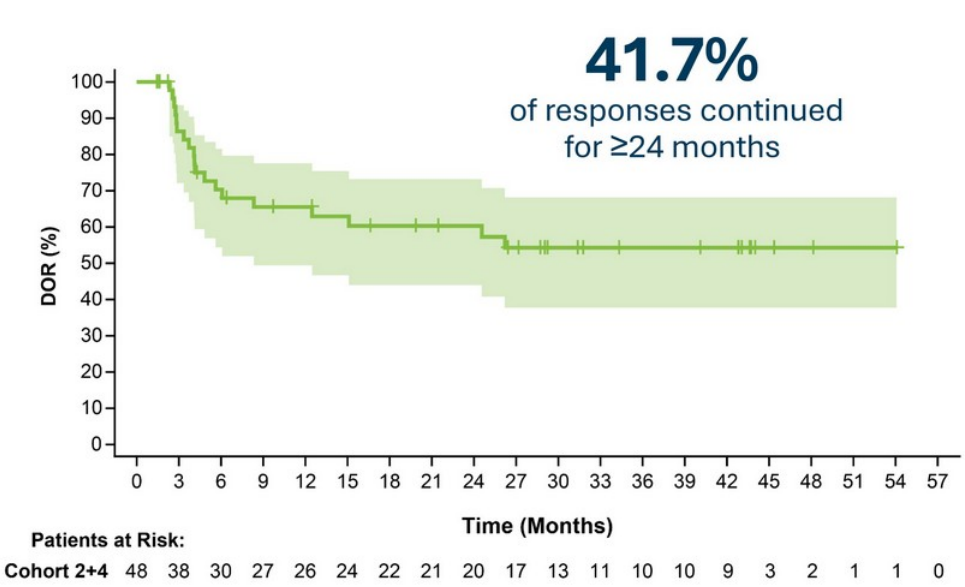
- **Median time from lifileucel infusion to best response was 1.5 months**
- **Responses deepened over time**
  - 7 patients (14.6%) initially assessed as PR were later confirmed CR
  - 4 patients (8.3%) converted to CR >1yr post-lifileucel infusion; 2 (4.2%) of 4 patients converted after 2 years
  - 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)	Coho (n=
Median follow-up, months	**45.1**	**33**
95% CI	(44.2, 51.4)	(30.4,
Median DOR†, months	**NR**	**10**
95% CI	(NR, NR)	(4.1,
Min, max (months)	1.4+, 54.1+	1.4+,
DOR ≥12 months, n (%)	**15 (65.2)**	**11 (4**
DOR ≥24 months, n (%)	**11 (47.8)**	**9 (3**

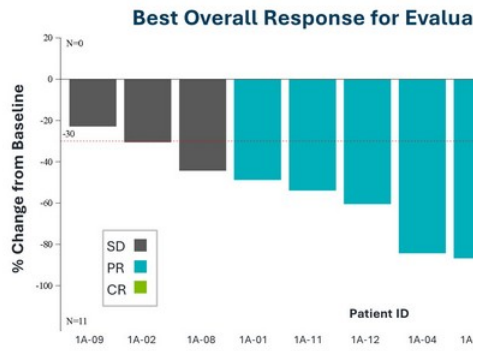
*Patients not experiencing PD or who did not die prior to the time of data cut had their event times censored at the last adequate tumor assessment. For patients who received new anticancer therapies, DOR was censored at the date of last tumor response assessment prior to the start of new anticancer 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

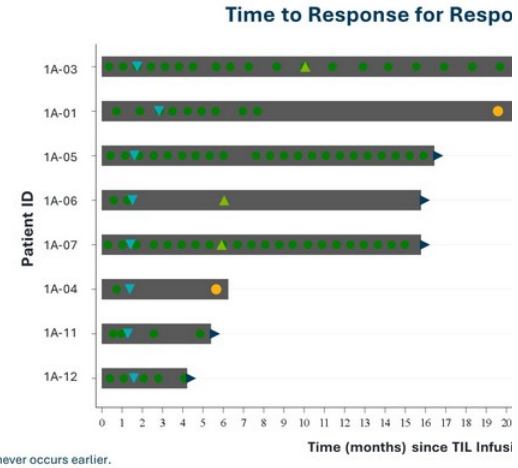
Iovance TIL Clinical Highlights in Combination with Pembrolizumab in Metastatic Melanoma

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



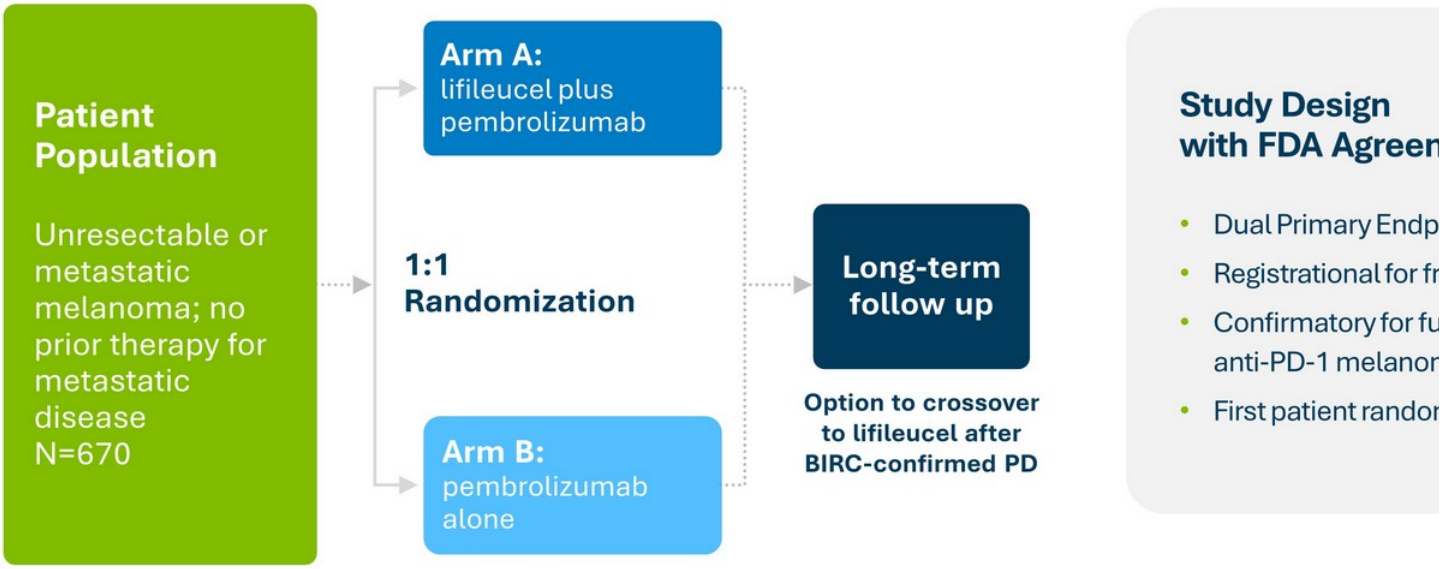


1. As assessed by investigator using RECIST 1.1 (January 20, 2022 data cutoff)
2. Each bar is presented for each patient starting from date of TIL infusion up to date of new anti-cancer therapy, end of assessment, death, or data cutoff date, whichever occurs earlier.

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

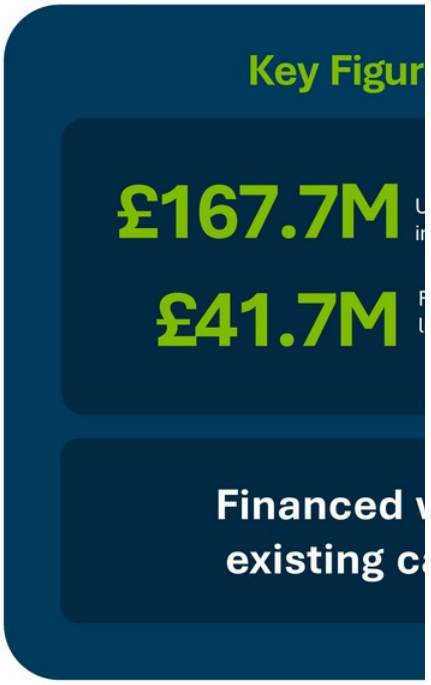


Abbreviations: BIRC, blinded independent review committee; ORR=objective response rate; PD=progressive disease; PD-1, programmed cell death protein-1; PFS=progression free survival

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



Iovance TIL Therapy in Non-Small Cell Lung Cancer

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

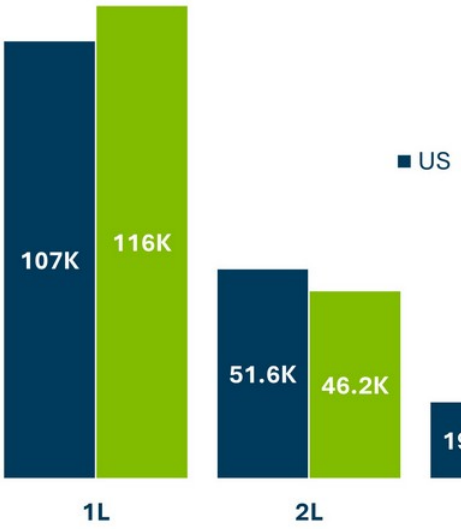
127K annual deaths in U.S.[1]

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 Popula

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)*

Patient Population

Unresectable or metastatic NSCLC with progression on or after prior anti-PD-1 treatment and chemotherapy

~40 sites and expanding in U.S., Canada, Europe

Registrational Cohorts

Cohort 1: NSCLC
Patients with < 1% or unknown TPS
LN-145

Cohort 2: NSCLC
Patients with ≥ 1% TPS
LN-145

Exploratory Cohorts

Cohort 3: Core Biopsy and Gen3††
LN-145

Cohort 4:
LN-145, pre-PD tumor harvest

Retreatment Cohort

IOV-LUN-202 is desig
patients with advance
with a high unmet me
but limited prior lines
post anti-PD-1 treatm

Endpoints

- Primary: ORR by IRC
- Secondary: Safety

* U.S. FDA placed a 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

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)

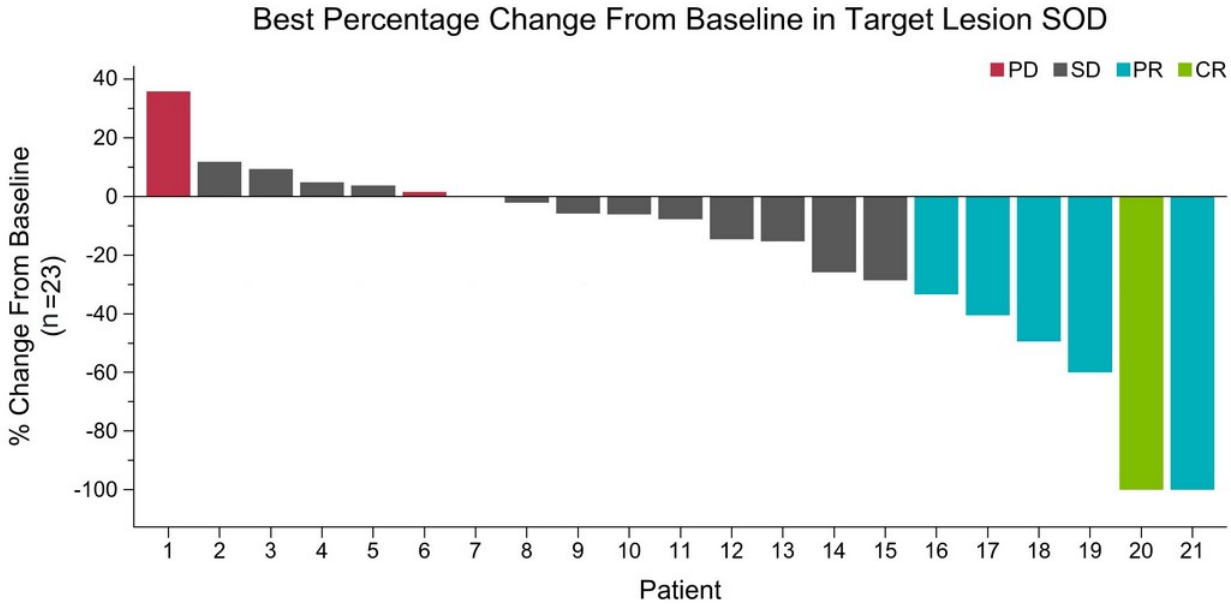
TEAEs were consistent with the underlying disease and known AE profiles of NMA-LD and IL-2

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

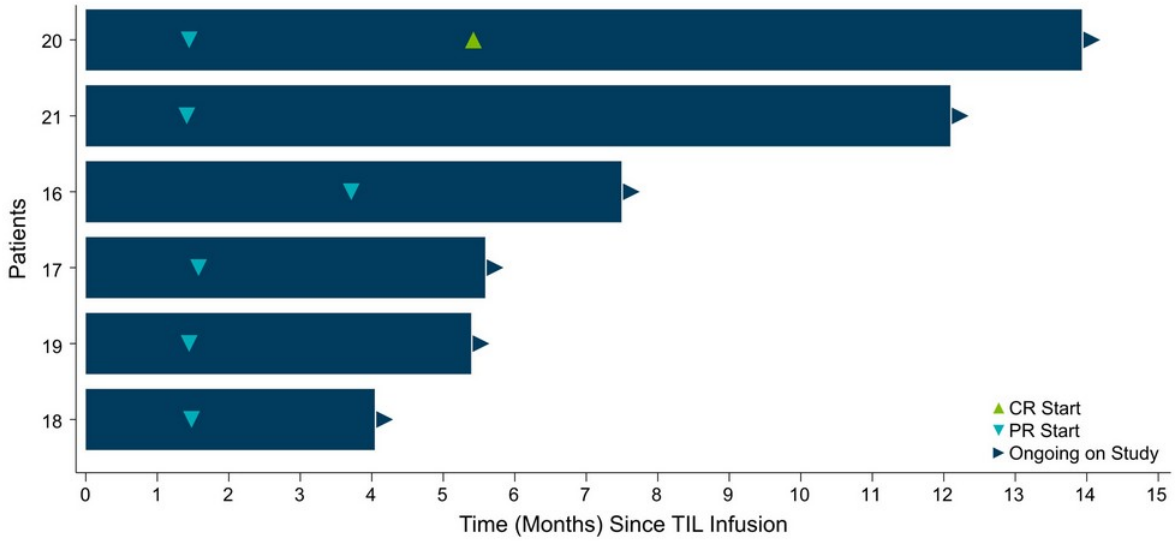
Objective Response Rate of 26.1% by RECIST 1.1, Regardless of PD-L1 Status



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 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]

- 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

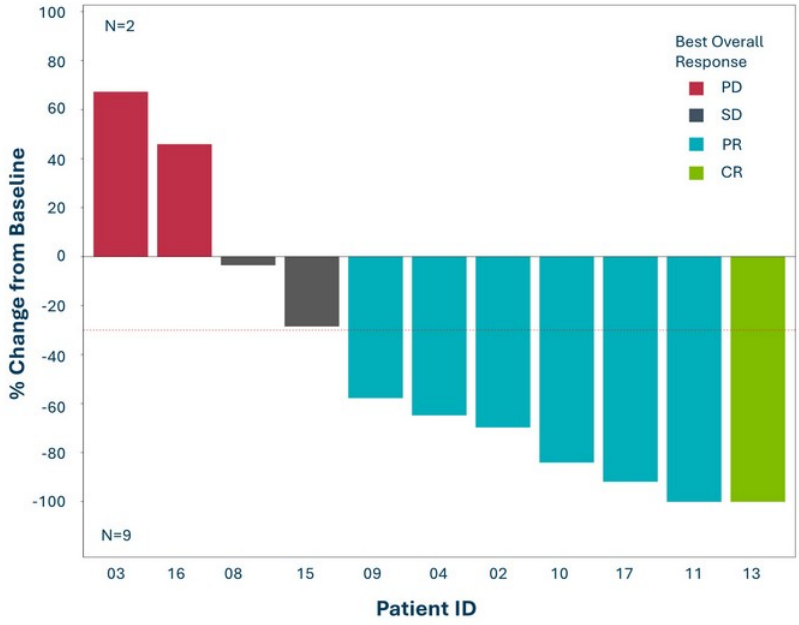
Cohort 3A Results Support A
Therapy to Frontline Pembroli
Chemotherapy Combination F

1. Schoenfeld, et al. WCLC 2023

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

Best Response and Percent Change in Target Lesion SOD

TIL Activity Across ICI Naïve Subgroups and TPS Scores, Including 58.3% ORR in Patients with EGFR^{WT} Dis



Best Overall Response	Cohort 3A EGFR^{WT} Patients (N=12)	
	n/N	% (95% CI)
ORR	7	58.3 (27.7, 84.8)
DCR	9	75.0 (42.8, 94.5)
CR	1	8.3
PR	6	50.0
SD	2	16.7
PD	2	16.7
NE	1	8.3

- Cohort 3A ORRs by prior therapy:
  - Treatment-naïve: 80% (4/5)
  - Post-chemotherapy: 42.9% (3/7)
- Anti-PD-1 monotherapy benchmarks[1]:
  - Treatment-naïve: 27% (TPS ≥ 1%); 3
  - Post-chemotherapy: 18 - 20%

1. KEYTRUDA USPI; OPDIVO USPI

Abbreviations: CR, complete response; DCR, disease control rate; EGFR, epidermal growth factor receptor; ICI, immune checkpoint inhibitor; NE, non-evaluable; NSCLC, non-small-cell lung cancer; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease; SOD, sum of diameter; TPS, tumor proportion score; WT, wild-type

Time on Study for Confirmed EGFR^{WT} Responders (n=7)

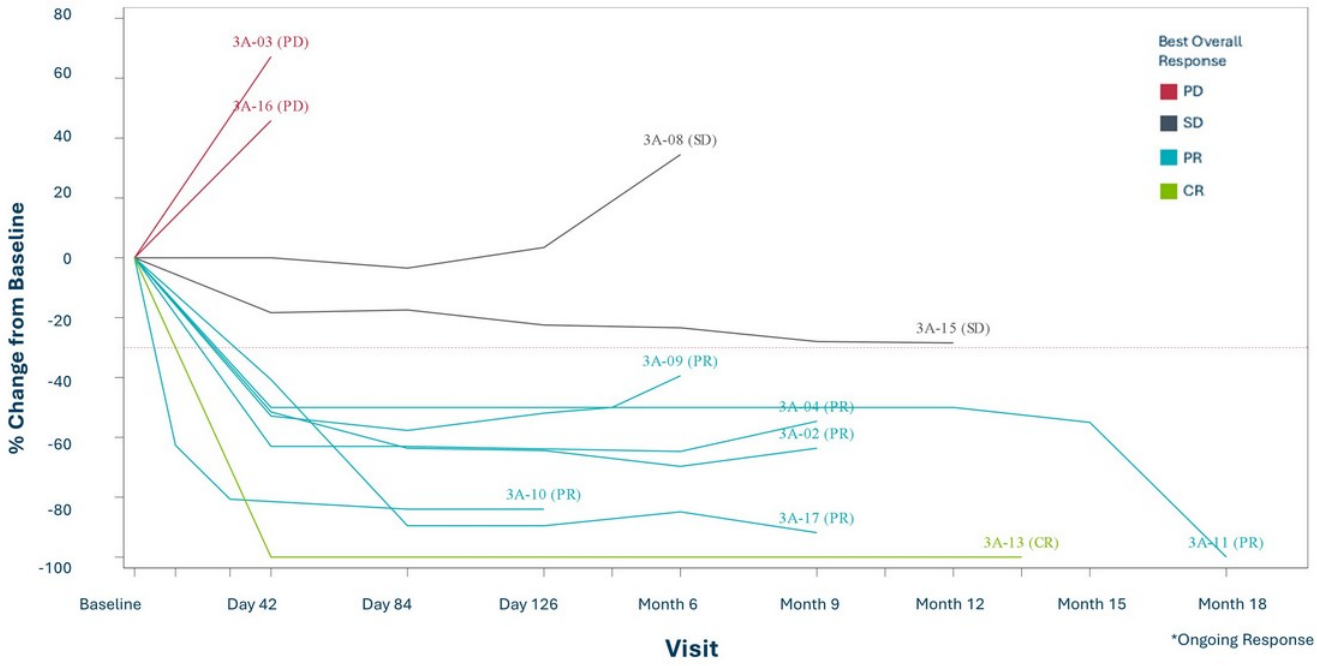
Durable Responses Include 3 Ongoing Responders with EGFR^{WT} Disease at a Median Study Follow up of 1

Pt ID	Prior ICI	Prior Chemo	PD-L1 TPS[a] (%)	SQ or NSQ	BOR
11	No	Yes	<1	NSQ	PR
13	No	Yes	<1	NSQ	CR
2	No	No[b]	<1	NSQ	PR
4	No	No	≥50	NSQ	PR
17	No	No	≥50	SQ	PR
9	No	Yes	<1	NSQ	PR
10	No	No	≥50	NSQ	PR

A bar for each patient starts 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. Patient received prior neoadjuvant chemoradiotherapy
Abbreviations: BOR, best overall response; CR, complete response; NSCLC, non-small-cell lung cancer; NSQ, nonsquamous; ORR, objective response rate; PD-L1, programmed death ligand 1; PR, partial response; Pt, patient; SOD, sum of diameters; SQ, squamous; TPS, tumor proportion score; WT, wild-type

Change in Target Lesion SOD in EGFR^{WT} Patients (n=11)

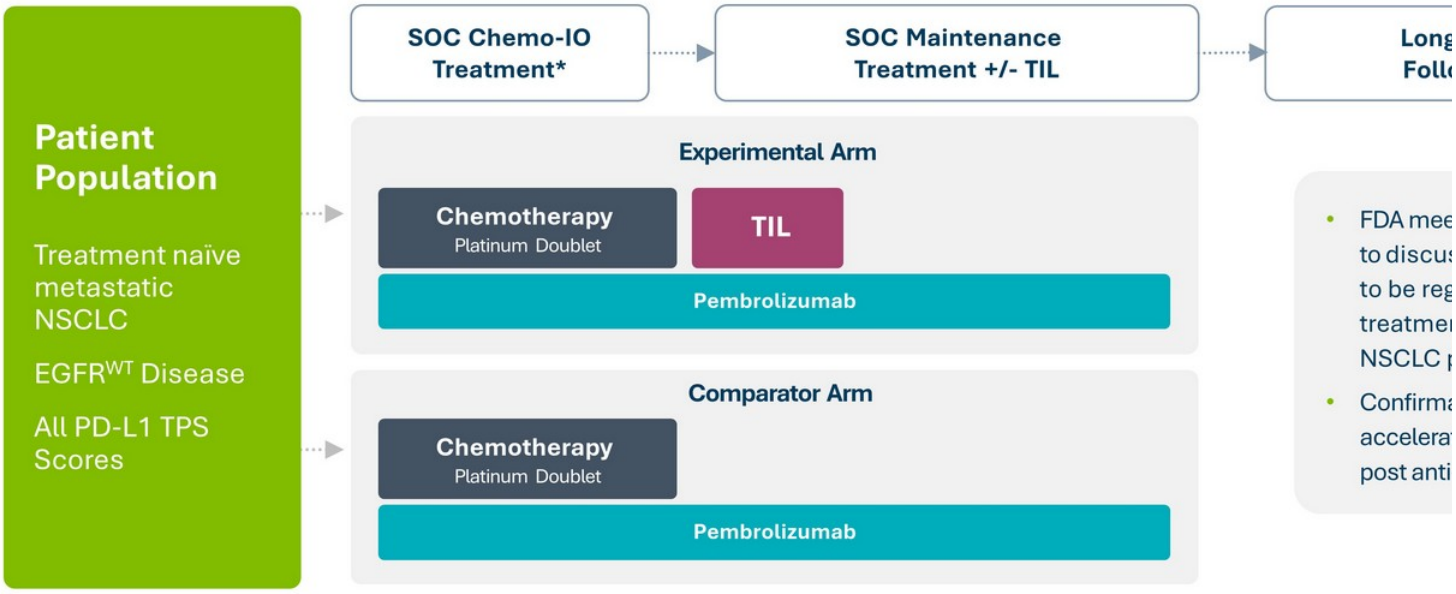
Deepening of Responses Over Time are Characteristic of One-Time Immunotherapy



Abbreviations: CR, complete response; EGFR, epidermal growth factor receptor; NSCLC, non-small-cell lung cancer; PR, partial response; SD, stable disease; PD, progressive disease; WT, wild-type

Frontline NSCLC Registrational Trial: Design Supported by Cohort

Adding TIL Therapy to Standard-of-Care Therapy

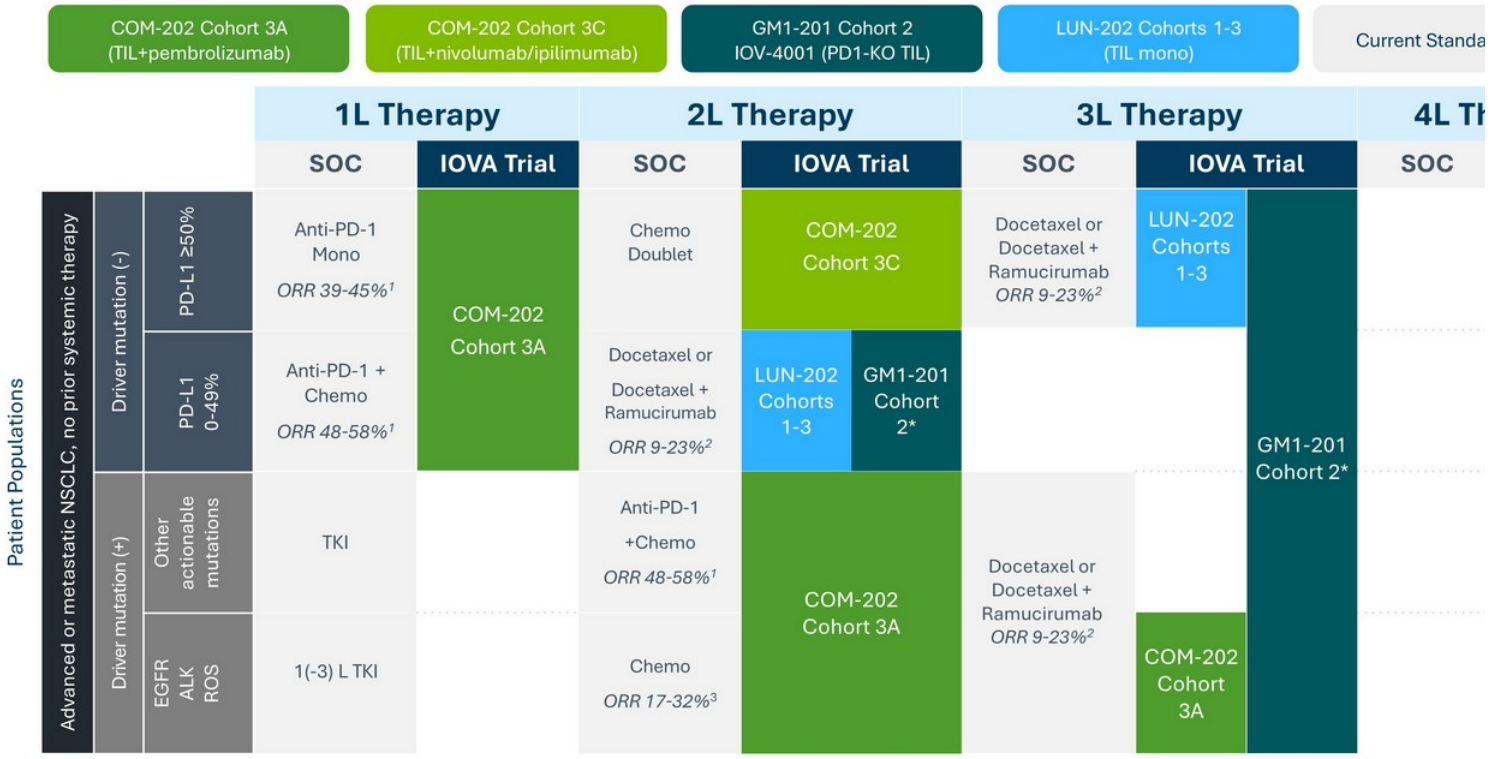


Benchmarks	EGFR/ALK status	ORR	mDOR (mos)	mPFS (mos.)	Prior IO	Prior Chemo	PD-L1 (%)	SQ or NSQ
Keynote-189[1,2]	WT	48%	11.2	8.8	No	No	All	NSQ
PD-L1 <1 Subgroup[1,2]	WT	32%			No	No	<1	NSQ
Keynote-407[1]	N/A	58%	7.2	6.4	No	No	All	SQ

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

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

Moving TIL Therapy into Relevant Lines of Therapy in NSCL



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. KEYTRUDA USPI; 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

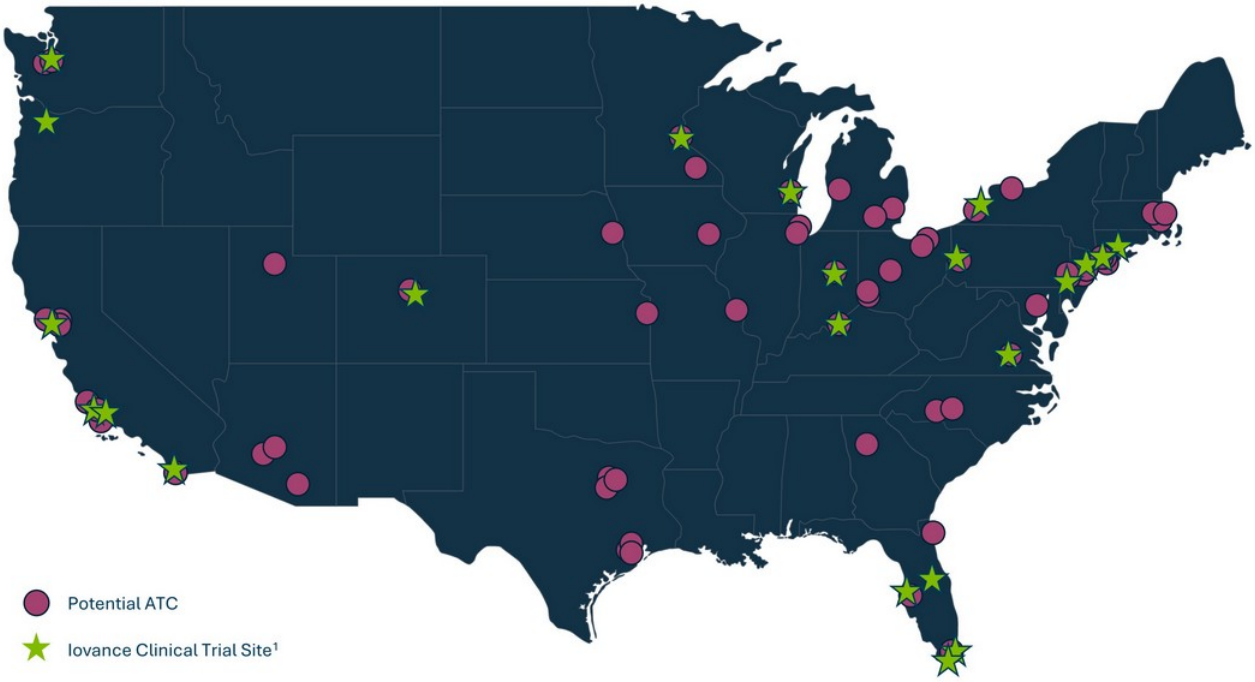
Launch Preparation

*i*CTC 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)

~30 ATCs Completed Pre-Approval Onboarding; ~50 ATCs Expected 90 Days Post-PDUFA



Targeting
Consider

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

Drive Der

- Top acco
- Commur

1. ClinicalTrials.gov

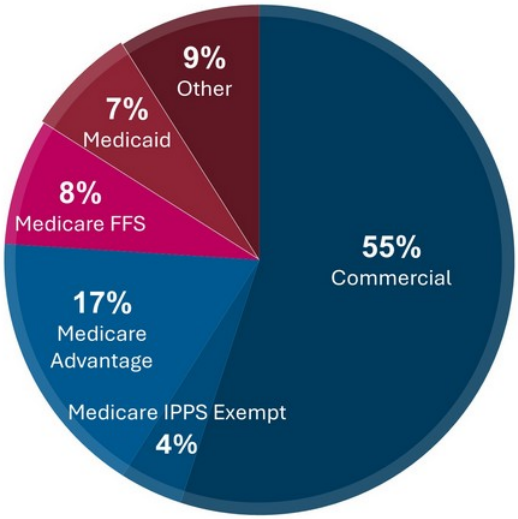
Abbreviations: ATC=Authorized Treatment Centers; NCCN=National Comprehensive Cancer Network; KOL=Key Opinion Leaders; BMT=Bone Marrow Transplant

Enabling Market Access

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

Metastatic Melanoma Payer Mix[1]

All Treatment Settings and Lines of Therapy

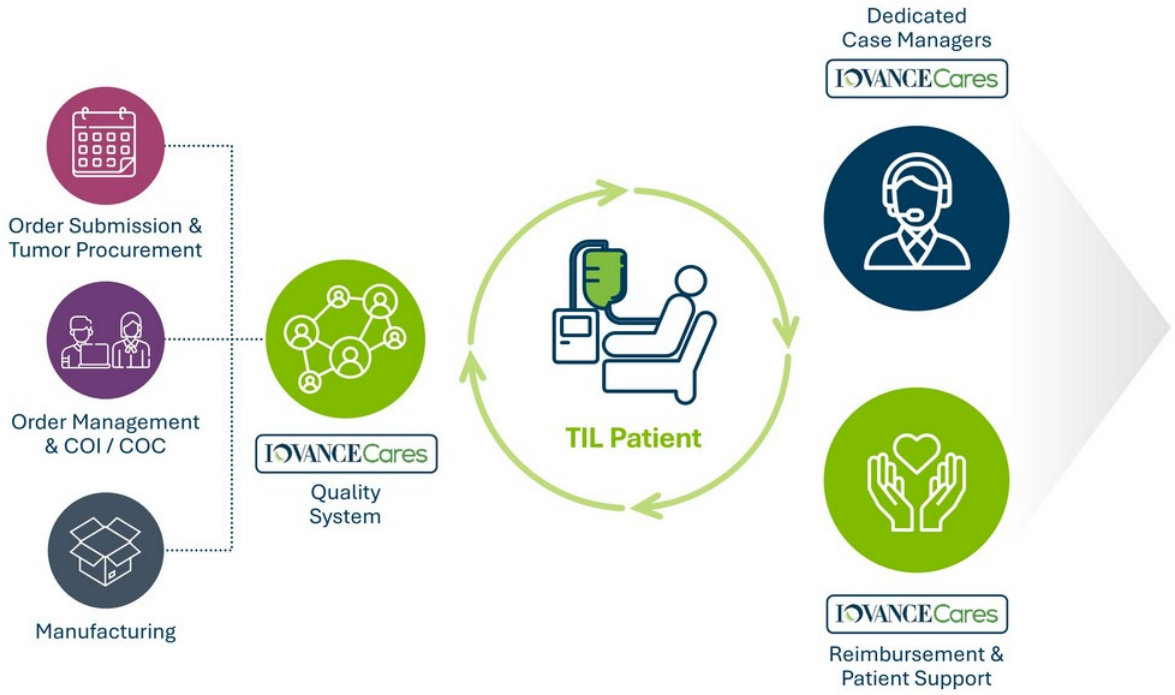


Anticipated Access

- 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

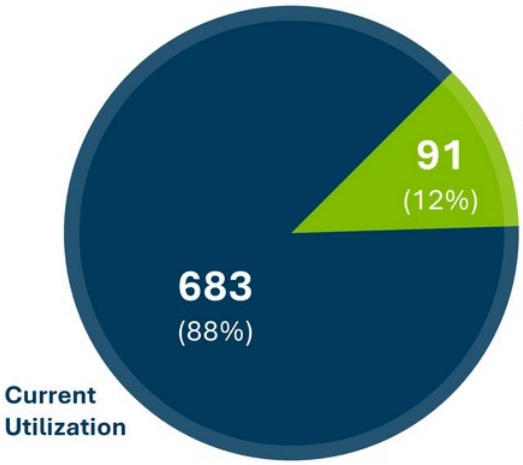
- Dedicated case
- Reimbursement
- Patient support p

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

Hospital Bed Capacity Supports Broad Lifileucel Adoption

HHS data and Iovance onboarding assessments reinforce ample oncology beds

Average Beds per Target ATC[1]



Hospital Bed Capacity

- HHS data reinforce sufficient overall availability at target ATCs[1]
  - Average of ~ 91 available beds per tar
- Target ATCs report sufficient oncolog availability for anticipated lifileucel d
  - Average of ~25 available beds per targ month suitable for lifileucel patients
  - Multi-disciplinary teams of clinicians administrators invest significant resou TIL cell therapy service lines
- Over half of target ATCs report ongoir investments that will increase inpatie

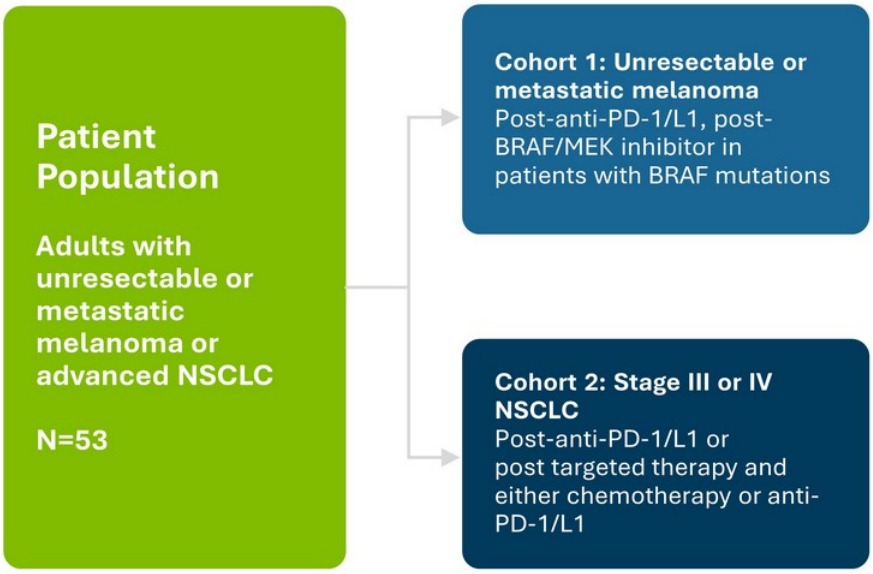
Note: Oncology/cell therapy beds are a subset of the total available hospital beds
Abbreviations: ATC=Authorized Treatment Center; HHS=U.S. Department of Health and Human Services; TIL=tumor infiltrating lymphocytes
1. HHS, Daily avg bed capacity and utilization at target centers (all types of hospital beds): Jan 2022-Mar 2023, https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/anag-cw7u
2. Iovance primary market research, 2022-2023
3. Iovance secondary market research, 2023

Other TIL Therapy Clinical Program Highlights

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)



Endpoints

- Phase 1: Safety
- Phase 2: Objective Respons
  RECIST v1.1 as assessed by
- Secondary endpoints includ
  response (CR) rate, duration
  (DOR), disease control rate (
  progression free survival (PF
  survival (OS), safety and tole

Study Updates

- 3Q22: first patient treated

NSCLC=non-small-cell lung cancer

Potential Market for Cervical Cancer

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

604k New cases WW each year[1]

342k Deaths WW each year[1]

14k Diagnoses in U.S. each year[2]

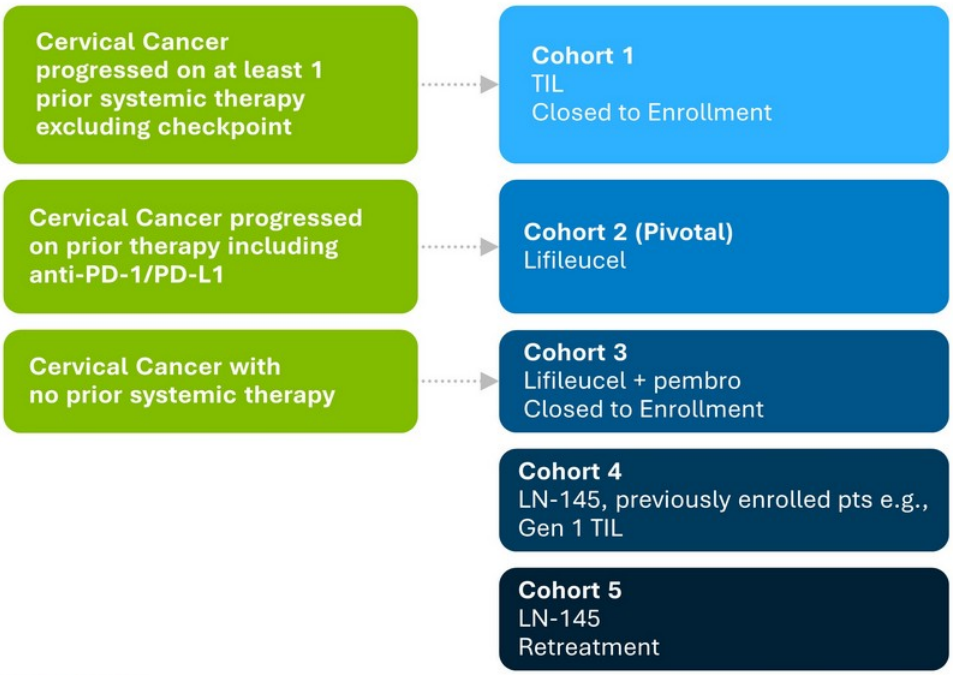
4k Deaths in U.S. each year[2]

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 Persis Cervical Carcinoma (NCT03108495)

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



Endpoints (Pivotal C

- Primary: ORR as determi
- Secondary: safety and ef

Study Updates

- 4Q21: initial Cohort 3 da
- 3Q22: Expanded Cohort regulatory submissions

1. O'Malley et al., SITC 2021

Next-Generation Research Programs

Trailblazing Next-Generation TIL Programs

Genetically modify TIL

Cellectis 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 TILs[3]

Next-generation processes

Gen 3 (16-day) process

Core biopsy

Exp ne

IO ana from ena

Corporate Summary & Milestones

Well-Capitalized in Pursuit of TIL Commercialization

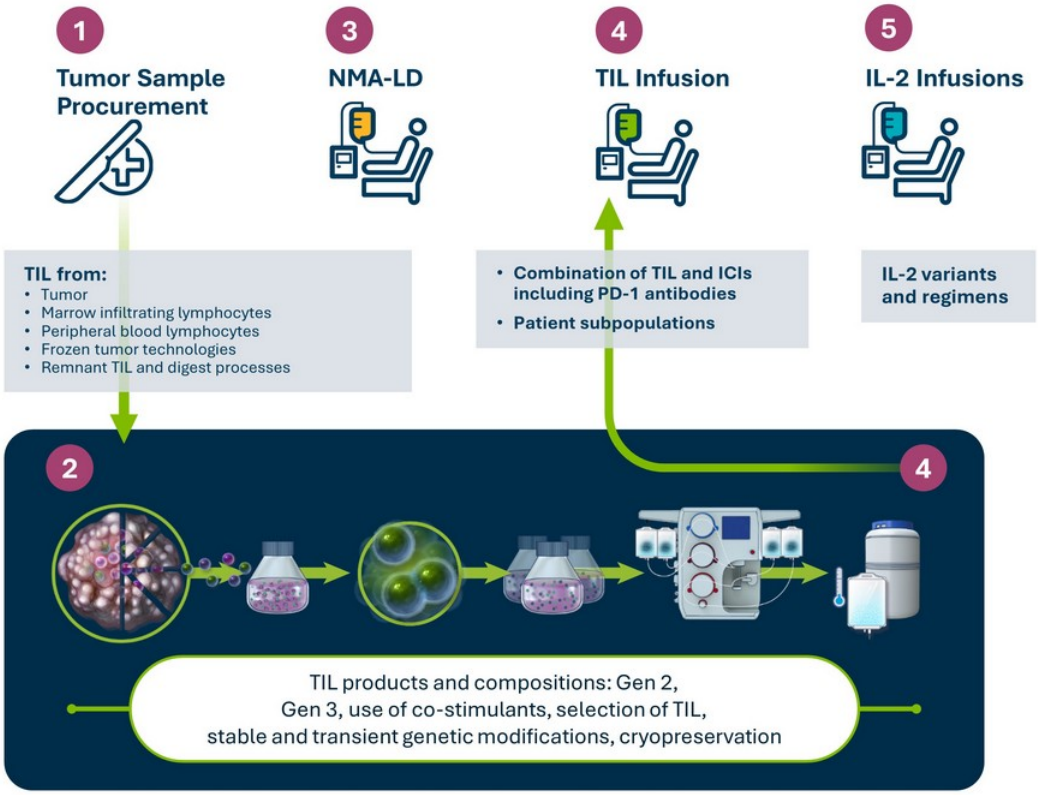
September 30, 2023	(in millions)
Cash, cash equivalents, investments, restricted cash	$427.8[1]
Common shares outstanding	255.8
Preferred shares outstanding	2.9[2]
Stock options and restricted stock units outstanding	23.1

Cash runway is sufficient into 2025*

** Includes anticipated revenue in 2024 from lifileucel and Proleukin®*

1. Includes Restricted Cash of $66.4 million as of September 30, 2023.
2. Preferred shares are shown on an as-converted basis

Broad, Iovance-Owned IP Around TIL Therapy



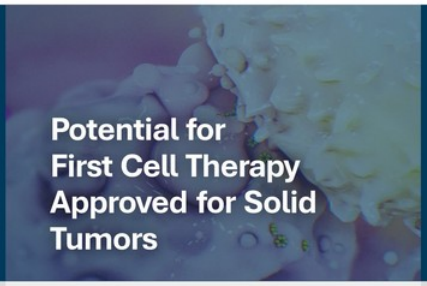
- 60+ granted c and internatic
- Compositions for TIL produc
- Methods of tr broad range c
- Manufacturin

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 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

- Iovance Cell Therapy Center (*i*CTC) in-house manufacturing
- Additional capacity with contract manufacturers
- Rapid 22-day Gen 2 manufacturing with 90%+ success rate
- >700 patients treated with Iovance proprietary process

Infrastr… Comme…

- Fully in…
- Experie… functio… therapy
- Partner… cancer… TIL serv…
- Iovance… proprie…
- Proleuk…

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.

2023 Milestones

REGULATORY	☑ BLA: Complete rolling BLA submission for lifileucel in post-anti-PD-1 advanced melanoma in C cycle meeting completed and BLA on track toward PDUFA date
	☑ Ex-U.S. regulatory submissions: Initiate preparation of submissions in ex-U.S. markets
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 trials
	☑ Cervical: enroll additional patients in registrational Cohort 2
	☑ Research: advance new products toward clinic, including additional genetically-modified TIL tl
MANUFACTURING	☑ Execute GMP commercial readiness activities to support BLA approval including passing PLI ir
	☑ Supply lifileucel at launch: Ramped up iCTC and CDMO capacity in preparation for launch
COMMERCIAL	☑ Prepare for commercial launch
	☑ Close transaction and successfully integrate Proleukin® business

Anticipated 2024 Milestones

REGULATORY

- ❑ Obtain FDA approval for lifileucel in advanced melanoma (PDUFA date: February 24, 2024)
- ❑ Submit EMA regulatory submission in 1st half of 2024
- ❑ Submit additional ex-US submissions in 2nd half of 2024
- ❑ 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

IOVANCE
BIOTHERAPEUTICS

Thank You

ADVANCING IMMUNO-ONCOLOGY