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 8, 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 August 8, 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 is incorporated herein by reference.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.	Description
99.1	Iovance Biotherapeutics, Inc., Corporate Presentation – August 8, 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: August 9, 2024

Iovance Biotherapeutics, Inc.

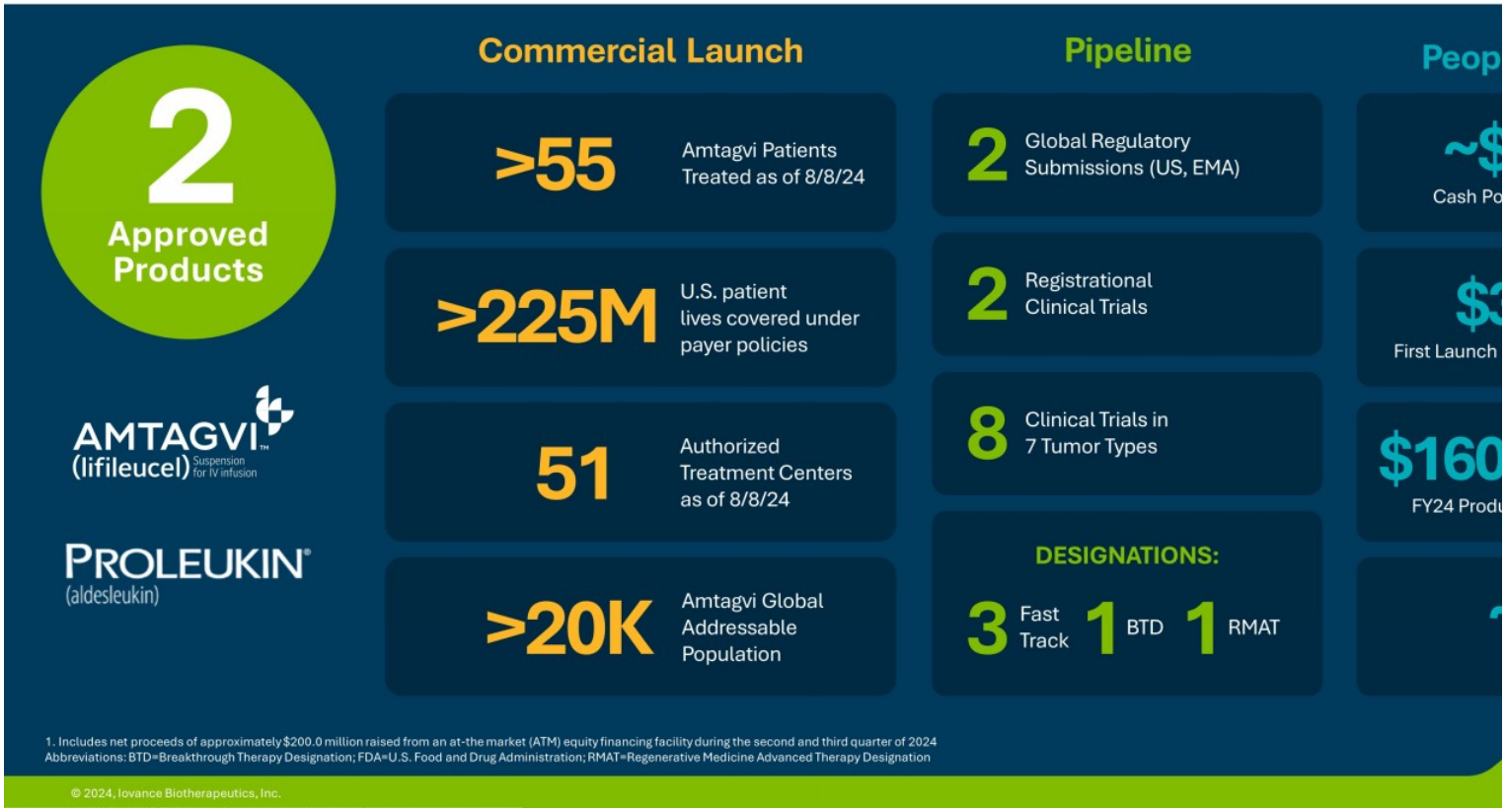
By: /s/ Frederick G. Vogt
Name: Frederick G. Vogt, Ph.D., J.D.
Title: Interim CEO and President, and General Counsel


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

Forward-Looking Statements

Certain matters discussed in this press release are “forward-looking statements” of Iovance Biotherapeutics, Inc. (hereinafter referred to as the “Company,” “we,” “us,” or “ of the Private Securities Litigation Reform Act of 1995 (the “PSLRA”). Without limiting the foregoing, we may, in some cases, use terms such as “predicts,” “believes,” “poter “estimates,” “anticipates,” “expects,” “plans,” “intends,” “forecast,” “guidance,” “outlook,” “may,” “can,” “could,” “might,” “will,” “should,” or other words that convey ur or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions and assessments made in light of managemer perception of historical trends, current conditions, expected future developments, and other factors believed to be appropriate. Forward-looking statements in this press rel date of this press 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-lo guarantees of future performance and are subject to risks, uncertainties, and other factors, many of which are outside of our control, that may cause actual results, levels of achievements, and developments to be materially different from those expressed in or implied by these forward-looking statements. Important factors that could cause actu and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the U.S. Securities and Excha including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknow inherent in our business: the risks related to our ability to successfully commercialize our products, including Amtagvi, for which we have obtained U.S. Food and Drug Admi approval, and Proleukin, for which we have obtained FDA and European Medicines Agency (“EMA”) approval; the risk that the EMA or other ex-U.S. regulatory authorities may approval for our marketing authorization application submission for lifileucel in metastatic melanoma; the acceptance by the market of our products, including Amtagvi and potential pricing and/or reimbursement by payors, if approved (in the case of our product candidates), in the U.S. and other international markets and whether such accepta continued commercialization or development of our products, including Amtagvi and Proleukin, or product candidates, respectively; future competitive or other market facto the commercial potential for Amtagvi or Proleukin; the risk regarding our ability or inability to manufacture our therapies using third party manufacturers or at our own facility increase manufacturing capacity at such third party manufacturers and our own facility, may adversely affect our commercial launch; the results of clinical trials with collab 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 succ commercialization of our products, including Amtagvi and Proleukin, may not generate sufficient revenue from product sales, and we may not become profitable in the near related to the timing of and our ability to successfully develop, submit, obtain, or maintain FDA, EMA, or other regulatory authority approval of, or other action with respect to whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authorities may support registrational studies and sub FDA, EMA, or other regulatory authorities, including the risk that the planned single arm Phase 2 IOV-LUN-202 trial may not support registration; preliminary and interim clini include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these tria cohorts; the risk that enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the risk that the chan cervical cancer patients may impact our clinical trials in this indication; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinic feedback from the FDA, EMA, or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA, EMA, or other differ from the interpretation of such results or communications by such regulatory authorities (including from our prior meetings with the FDA regarding our non-small cell l the risk that clinical data from ongoing clinical trials of Amtagvi will not continue or be repeated in ongoing or planned clinical trials or may not support regulatory approval o the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; the risk that we may not be for our products; the risk that Proleukin revenues may not continue to serve as a leading indicator for Amtagvi revenues; the risks regarding our anticipated operating and fina including our financial guidance and projections; the effects of global pandemic; the effects of global and domestic geopolitical factors; and other factors, including general regulatory developments, not within our control. Financial guidance as stated above in this press release assumes the following: no material change in our ability to manufa material change in payor coverage; no material change in revenue recognition policies; no new business development transactions not completed as of the period covered b no material fluctuation in exchange rates.

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



1. Includes net proceeds of approximately $200.0 million raised from an at-the market (ATM) equity financing facility during the second and third quarter of 2024
Abbreviations: BTD=Breakthrough Therapy Designation; FDA=U.S. Food and Drug Administration; RMAT=Regenerative Medicine Advanced Therapy Designation

Iovance Solid Tumor Portfolio Highlights

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

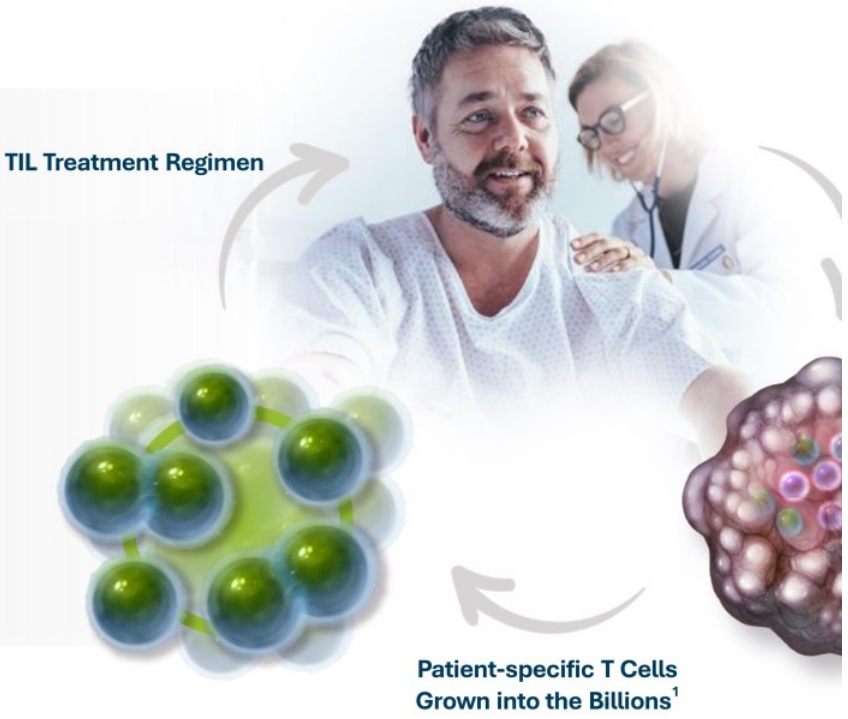
*Enrollment complete

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

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

TIL – Unique Proposed Mechanism of Action

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



1. Amtagvi USPI

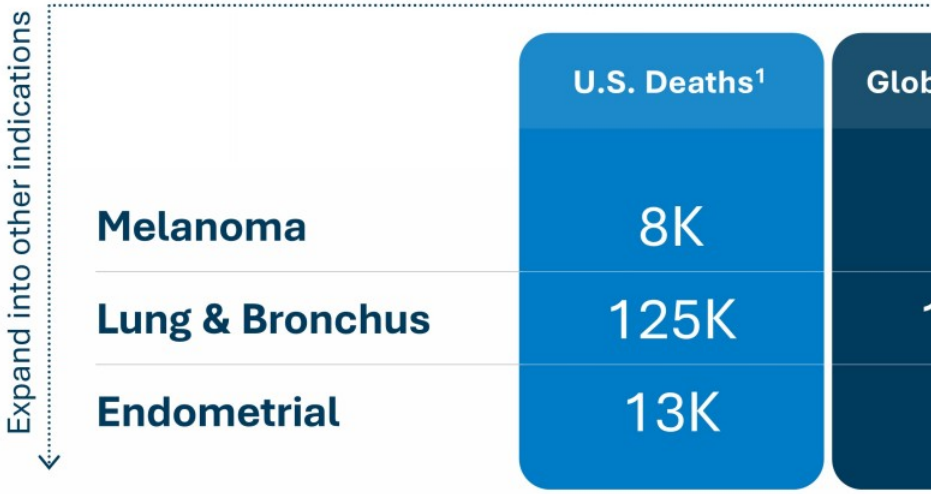
Significant Market Potential in Solid Tumors and our Key Pr

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. 2024 Estimates. https://seer.cancer.gov (accessed May 2024)
2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022

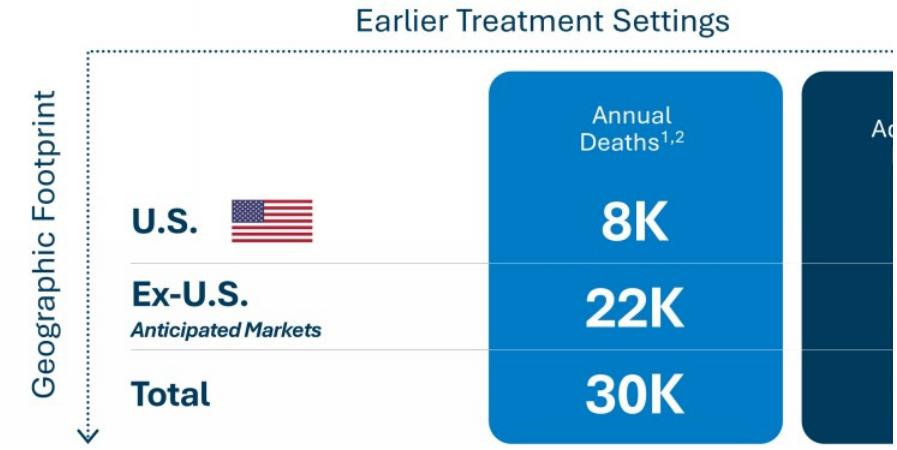
Significant Opportunity to Expand Advanced Melanoma Ma

Annual Addressable Opportunity in Previously Treated Advanced Melanoma[3]

>20K

Advanced Melanoma Treatment Expansion Opportunities[3]

>60K

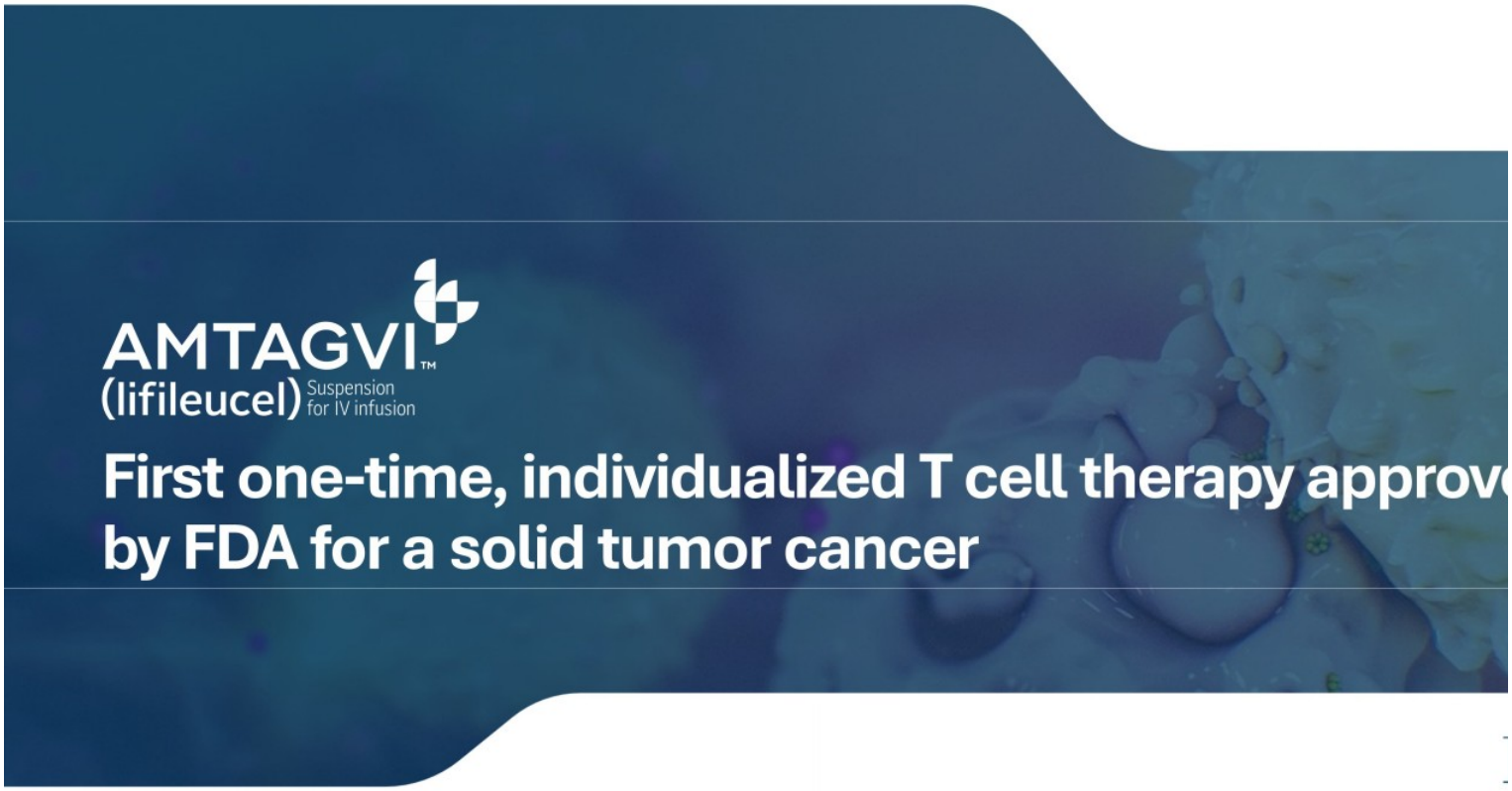


Initial Ex-U.S. Planned Regulatory Submissions:

UK: 2H 2024
EU: 2Q 2024
Canada: 2H 2024
Australia: 1H 2025

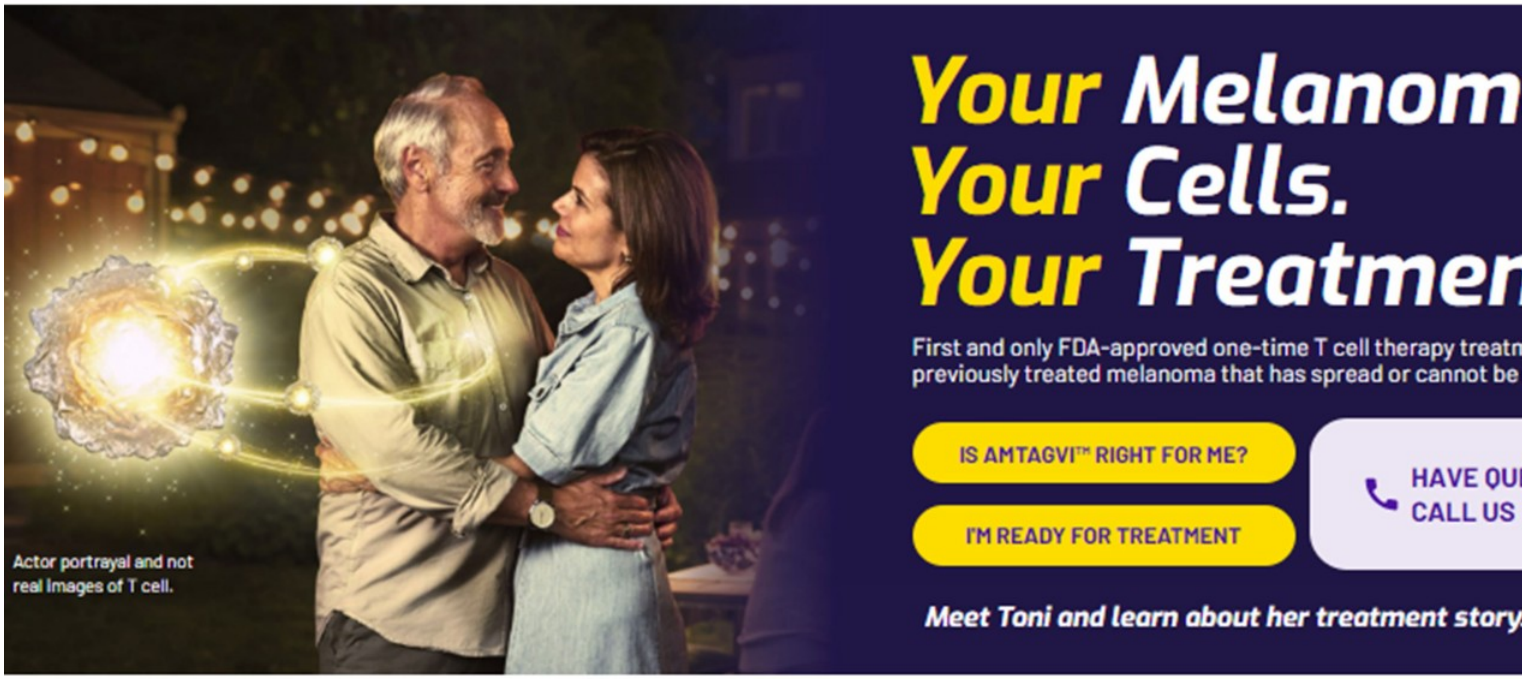
1H	2H	1H

1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2024 Estimates. https://seer.cancer.gov (accessed May 2024)
2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022
3. Data on file as of July 31, 2024



AMTAGVI™
(lifileucel) Suspension for IV infusion

Preferred second-line+ therapy in NCCN gui



1.National Comprehensive Cancer Network® Guidelines, Melanoma: Cutaneous, Version 2.24

Amtagvi™ Delivered Deep and Durable Responses

Cohort 4 Pivotal[1]
(n=73)

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

mDOR **Not Reach**
18.6 months foll
(Range: 1.4+, 26.3+; 95% CI: 4.1, N

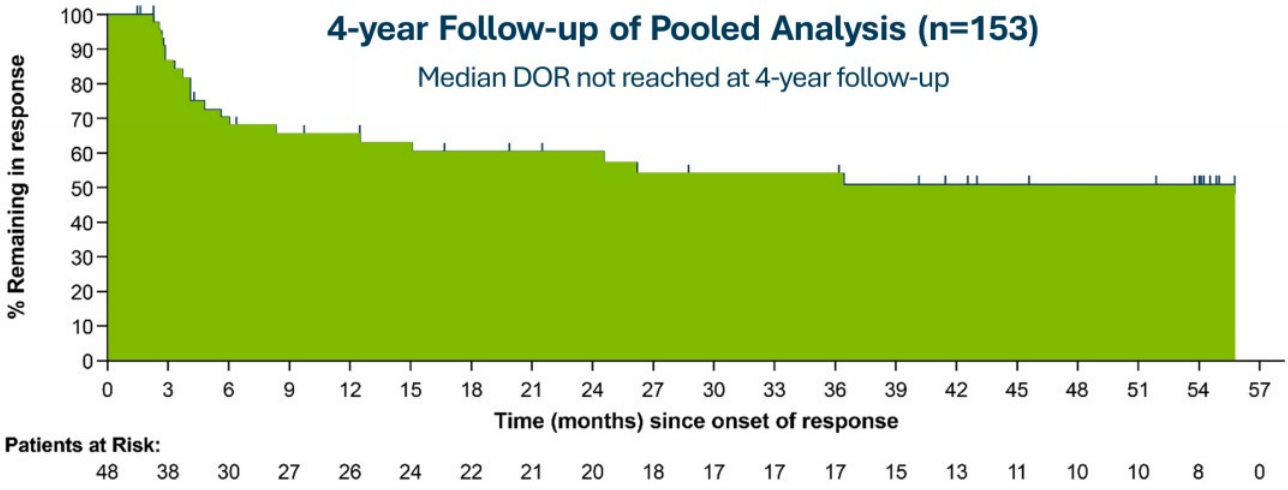
Supportive Pooled Data[1]
(n=153)

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

mDOR **Not Reach**
21.5 months foll
(Range: 1.4+, 45.0+)

1. C-144-01 Clinical Trial, Amtagvi USPI
2. Data on file.
Abbreviations: CI=confidence interval; mDOR=median duration of response; NR=not reached; ORR=objective response rate

Amtagvi™ Durability at 4-Years



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

ORR

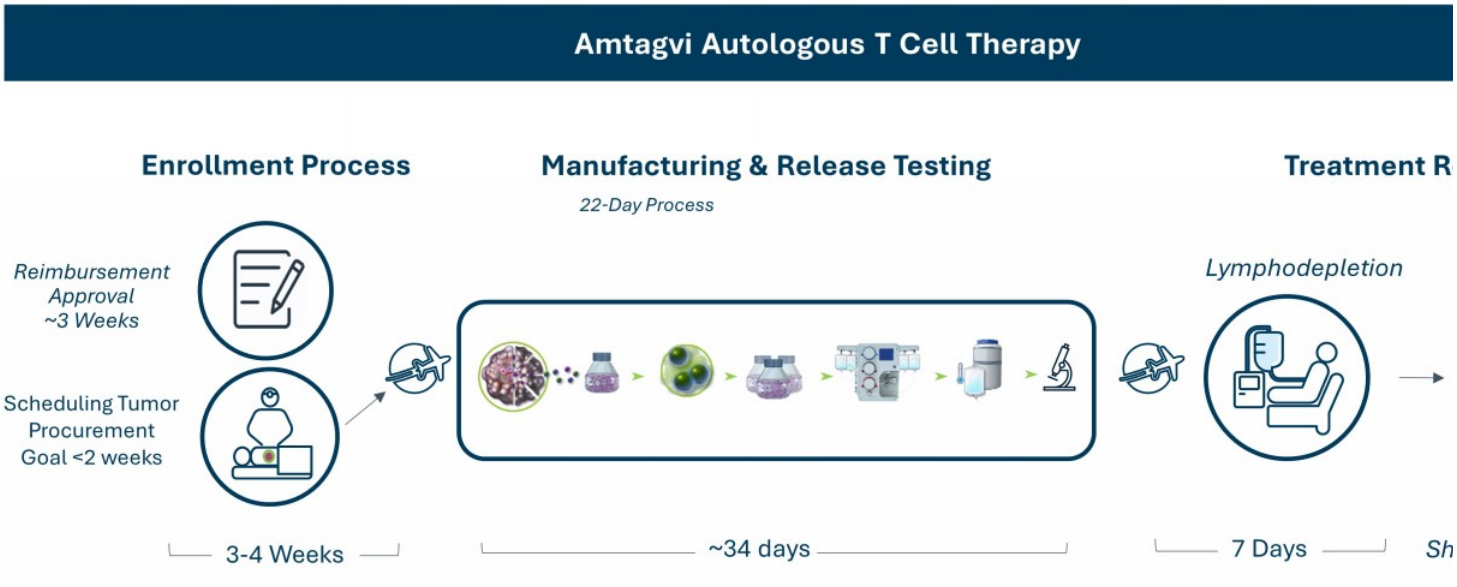
mDOR

4

1. Medina et al, ESMO IO 2023

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

Amtagvi™ Patient Journey



Time to treatment decreasing over time driven by faster reimbursement and scheduling, earlier lym

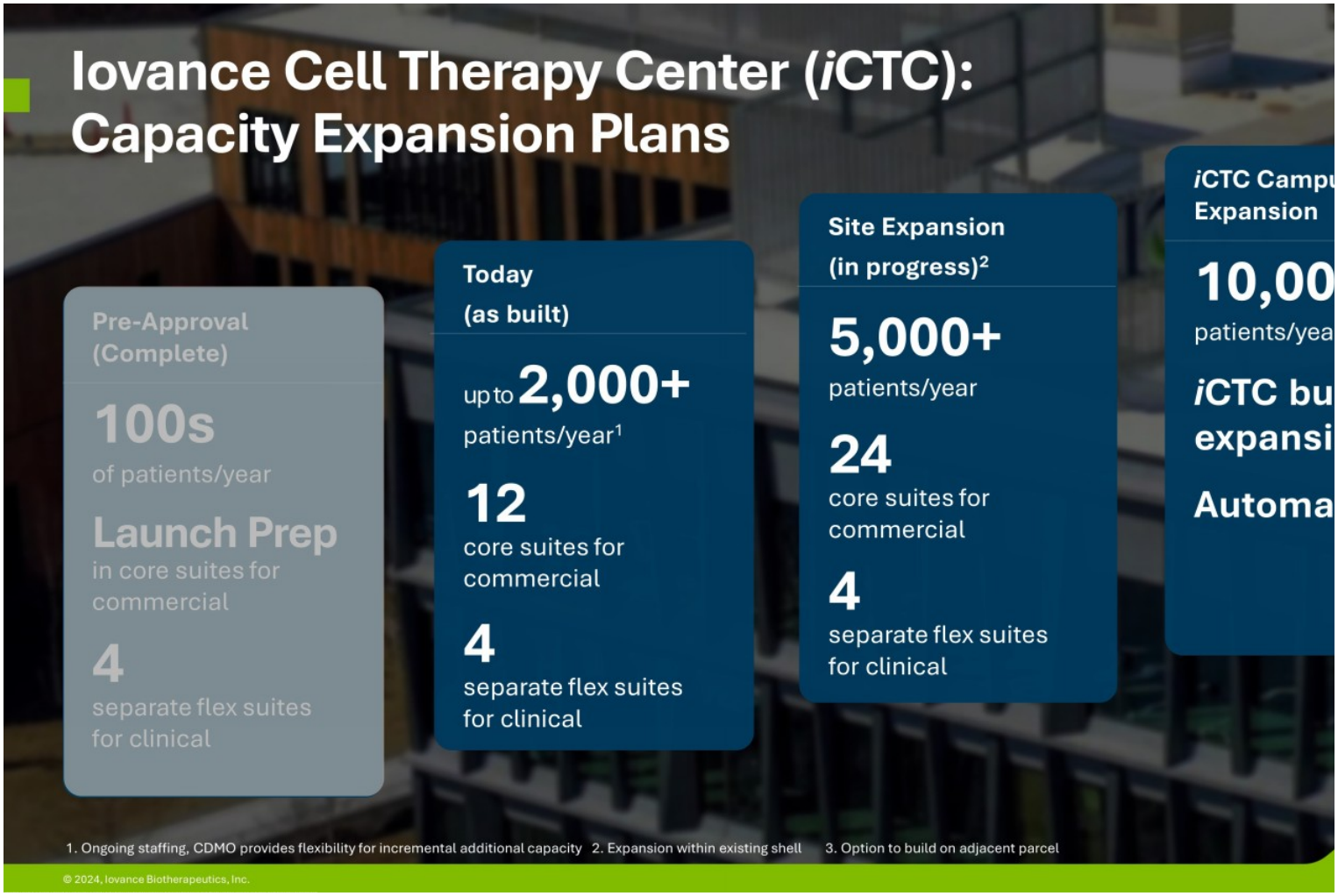
Iovance Cell Therapy Center: *i*CTC

- Built-to-suit custom facility in Navy Yard Philadelphia
- Commercial and clinical TIL therapy supply
- Expanding headcount in alignment with expected growth in demand
- Control to optimize capacity, quality & COGS

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

IOVANCE BIOTHERAPEUTICS
CELL THERAPY CENTER

FOYA 2
ISPE Facility of the Year Awa
CATEGORY WINNER
Honorable Mention


Iovance Cell Therapy Center (iCTC): Capacity Expansion Plans
Pre-Approval (Complete)
100s
of patients/year
Launch Prep
in core suites for commercial
4
separate flex suites for clinical
Today (as built)
up to 2,000+
patients/year1
12
core suites for commercial
4
separate flex suites for clinical
Site Expansion (in progress)2
5,000+
patients/year
24
core suites for commercial
4
separate flex suites for clinical
iCTC Campu Expansion
10,00
patients/yea
iCTC bu expansi
Automa
1. Ongoing staffing, CDMO provides flexibility for incremental additional capacity 2. Expansion within existing shell 3. Option to build on adjacent parcel
© 2024, Iovance Biotherapeutics, Inc.

Authorized Treatment Centers (ATCs)

Goal to ensure patients have geographic accessibility to ATCs

Amtagvi™ Authorized Treatment Centers[1]

90%
Of Addressabl
within 200 mile

51
ATCs in Augu

70
ATCs by Ye

1. Amtagvi.com Note: There are at least 50 authorized treatment centers; Not all authorized treatment centers may be listed on the locator tool (Last accessed August 7, 2024).
Abbreviations: ATC=Authorized Treatment Centers

Broad Market Access

Initial payer medical coverage policies consistent with Amtagvi label, clinical trials and NCCN guidelines

>225 Million

Patient Lives Covered, Majority of Patients have private coverage

~3 Weeks

Time to financial clearance

~75

of Amtagvi patien
private p

Data on file, as of July 31, 2024. Data on file.
Abbreviations: NCCN = National Comprehensive Cancer Network

Amtagvi™ Expansion Plans in Advanced Melan

LIFILEUCEL + PEMBROLIZUMAB IN FRONTLINE ADVANCED MELANOMA: IOV-COM-202 COHORT 1A

Unprecedented Rate, Depth & Durability of Responses in Frontline Advanced Melanoma[1]

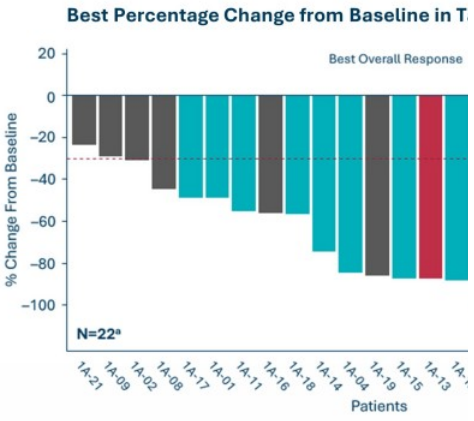
Data supports rationale for TILVANCE frontline study:

65.2%
ORR via RESCIST v 1.1

30.4%
CR

64%
PFS at 6 & 12 months

- Median PFS not reached at nearly 2 years of median follow-up
- mDOR Not Reached (median follow-up 21.7 months)
- All response-evaluable patients demonstrated regression of target lesions
- Safety consistent with underlying disease and known safety profiles of pembrolizumab, NMA-LD, lifileucel, and IL-2

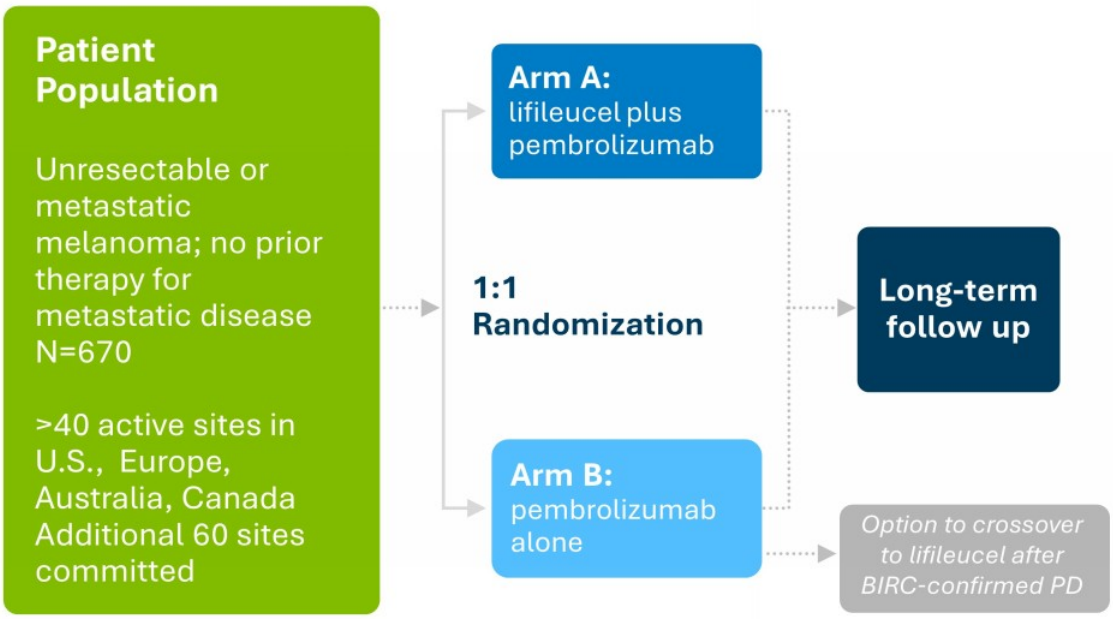


1. Thomas et al, ASCO 2024
*CR confirmed following data cut.
[a]One patient without a postdose tumor response assessment was not included. [b]Target lesion lymph node at baseline decreased by 50% is no longer pathological, and thus is shown here as -100% representing uCR. CI, confidence interval; CR, complete response; ORR, objective response rate; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SOD, sum of diameters; AE, adverse event; IL-2, interleukin-2; NMA-LD, nonmyeloablative lymphodepletion

LIFILEUCEL + PEMBROLIZUMAB IN FRONTLINE ADVANCED MELANOMA

TILVANCE-301 Global Phase 3 and Confirmatory Trial

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



Study Design with FDA Agreen

- Dual Primary Endp
- Interim analysis or
- Final analysis on P
- Registrational for fr
- Confirmatory for fu Amtagvi™ in post-a melanoma
- First patient randor

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

TIL Therapy Pipeline

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

Addressing a Substantial Unmet Need in Metastatic NSCLC

Iovance TIL clinical program:

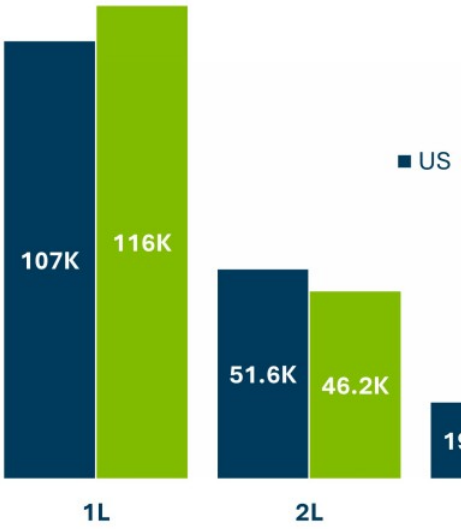
- 6 cohorts across 3 trials
- Multiple treatment regimens
- Various populations and stages of disease

125K annual deaths in U.S.[1]

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

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

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

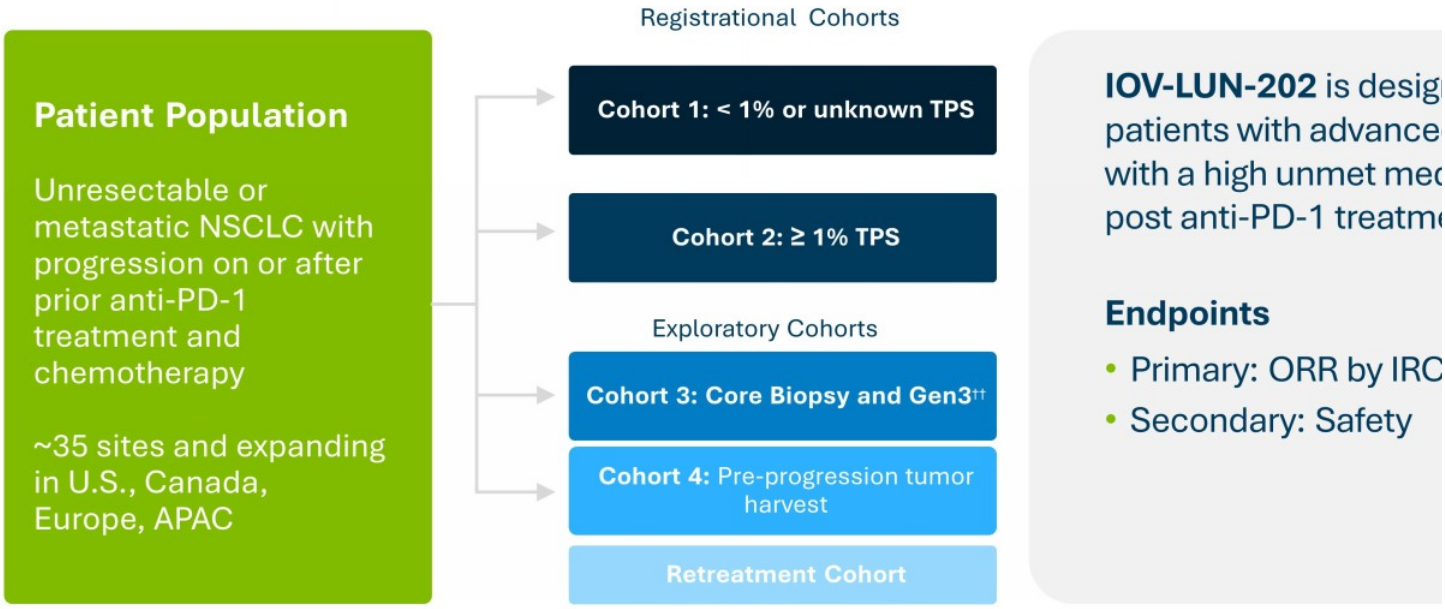


1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2024 Estimates. https://seer.cancer.gov (accessed May 2024)
2. American Cancer Society, Lung Cancer. https://www.cancer.org/cancer/types/lung-cancer/about.html (accessed May 2024)
3. National Cancer Database, NSCLC survival from >1 million patients assessed. Lou Y et al. Survival trends among non-small cell lung cancer patients over a decade: impact of initial therapy at academic centers. Cancer Med. 2018.
4. Clarivate DRG Disease Landscape (2021)

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

IOV-LUN-202 Registrational Trial Design

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



Enrollment completion and topline data for registrational cohorts anticipated

†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

IOV-LUN-202 COHORTS 1 AND 2, POST-ANTI-PD-1 NSCLC

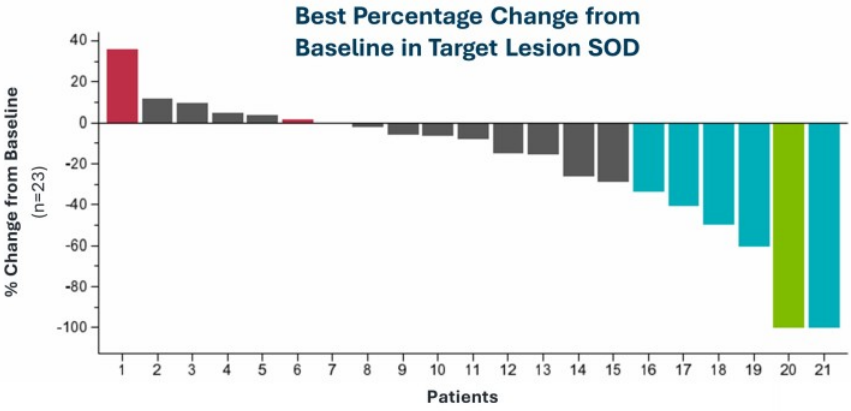
Strong Preliminary Clinical Results in Second-Line mNSCL

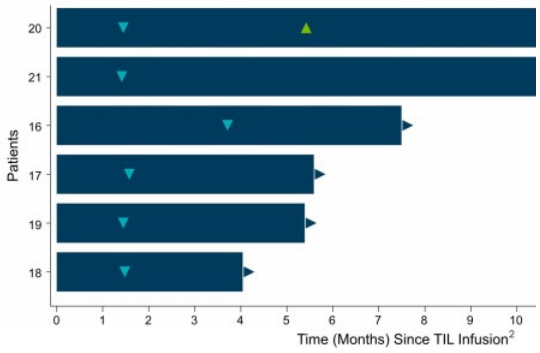
Tumor Reduction and Deep, Durable Responses in Previously Treated NSCLC, Regardless of PD-L1 Status

26.1% ORR

by RECIST 1.1, Regardless of PD-L1 Status

All responses remain ongoing at time of data cut





Data cut: July 6, 2023. 21 evaluable patients for response. Responses were assessed by investigator

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

Abbreviations: AE, adverse event; CI, confidence interval; CR, complete response; DOR, duration of 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; SOD, sum of diameters; TEAE, treatment-emergent AE; TPS, tumor proportion score.

LIFILEUCEL IN ADVANCED ENDOMETRIAL CANCER

Changing Treatment Landscape for Endometrial Cancer, a Immunosensitive Tumor Type

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

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

>90% of Uterine Cancers are Endometrial Cancers

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

67.8K
estimated new cases in U.S.[1]

18.9%
5-yr survival of women with distant metastases[1]

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

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

Pre bio en

dM (i.e., ~3/4

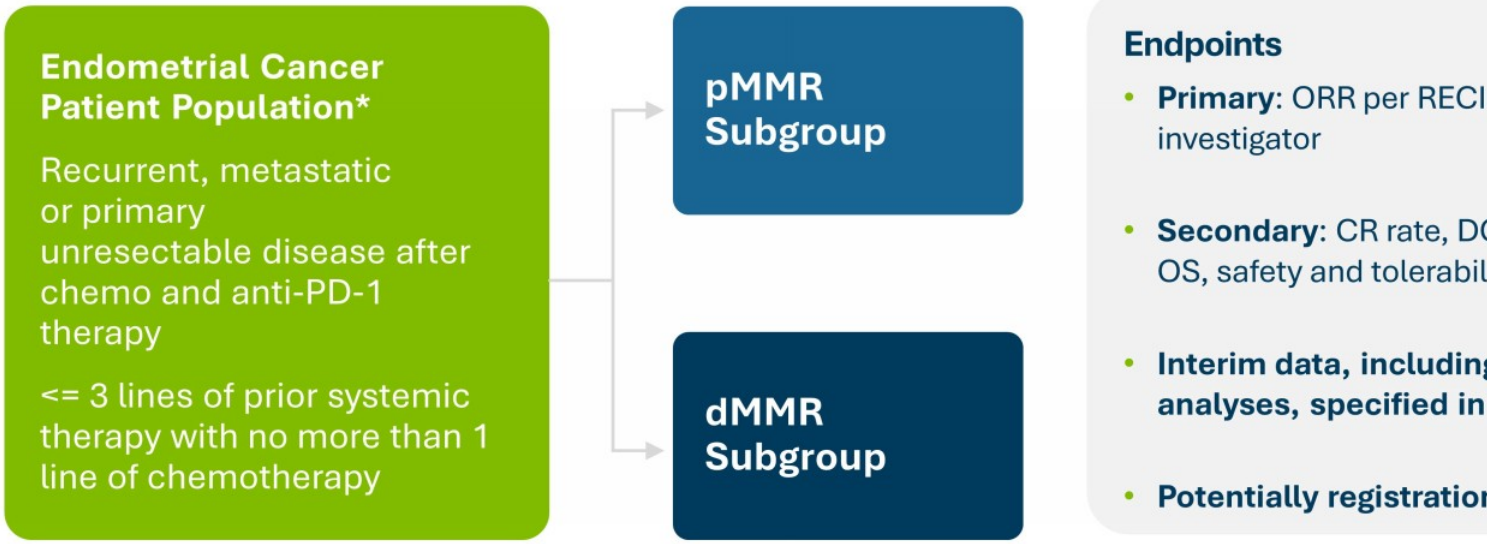
TN

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

LIFILEUCEL IN ADVANCED ENDOMETRIAL CANCER

IOV-END-201 Phase 2 Proof of Concept Study

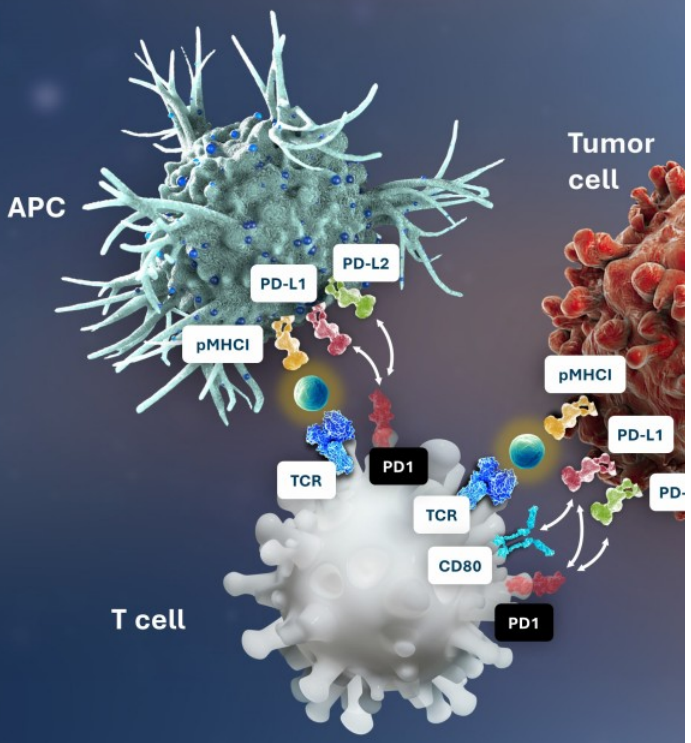
Proof-of-Concept Trial in Patients with Mismatch Repair Proficient and Deficient Tumors (NCT06481592)



*Sample size and study population of registrational ph2 study will be determined after PoC final analysis
Abbreviations: Anti-PD-1, anti-programmed cell death inhibitor; CR, complete response; dMMR, mismatch repair deficient; pMMR, mismatch repair proficient; DCR, disease control rate; DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression free survival

IOV-4001 - PD-1 Inactivated TIL Therapy

- Persistent antigen encounter in the tumor leads to upregulation of PD1 on antigen-specific T cells[1]
- PD1 engagement by its cognate ligands, PD-L1 and PD-L2, and downstream signaling negatively regulates the function of neo-antigen reactive T cells
- Deletion of PD1 in IOV-4001 serves to obviate the deleterious impact of PD1 engagement with signaling partners
- Exhibited superior antitumor activity in preclinical PDX model[2]
- Iovance continues to utilize TALEN® technology[3] to develop other investigational gene-edited TIL cell therapies with multiple knockout targets to potentially improve efficacy

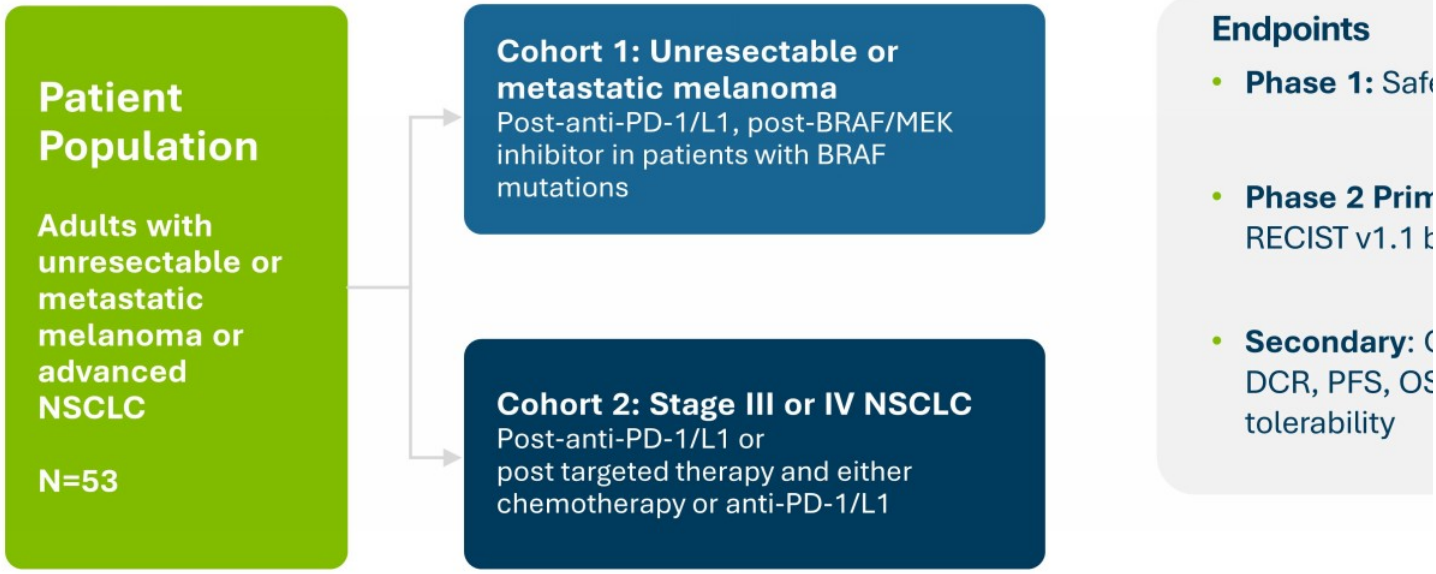


1. Sharpe AH, Pauken KE, Nat Rev Immunol 2018, 18:153-167
2. Natarajan A, Cubas R et.al. AACR 2022
3. Licensed from Cellectis

NEXT-GENERATION TIL THERAPY: IOV-4001

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

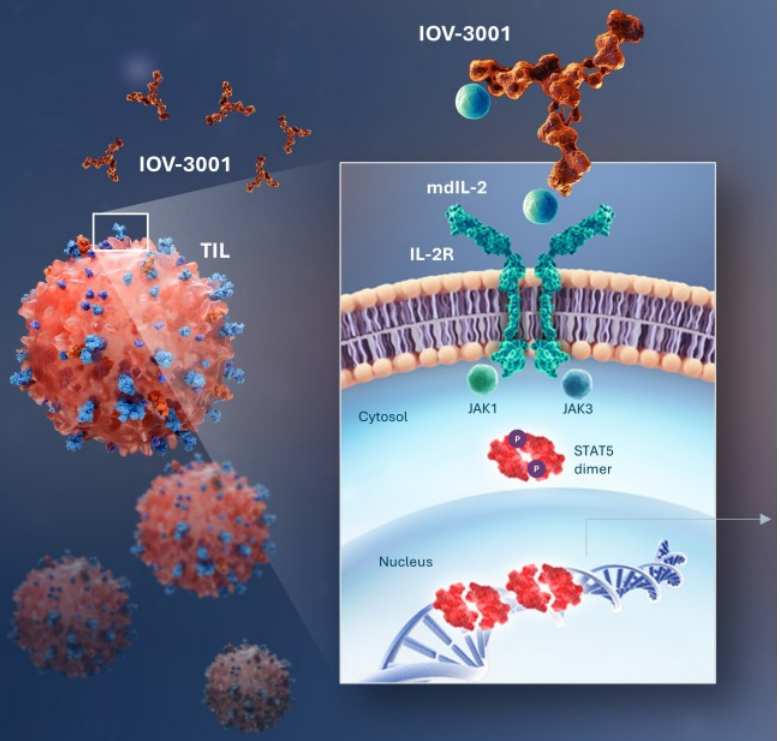
Genetically Modified, PD-1 Inactivated TIL Therapy IOV-4001 in Previously Treated Metastatic Melanoma a
(NCT05361174)



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

IOV-3001 – Next Generation IL-2 for TIL Supportive Regime

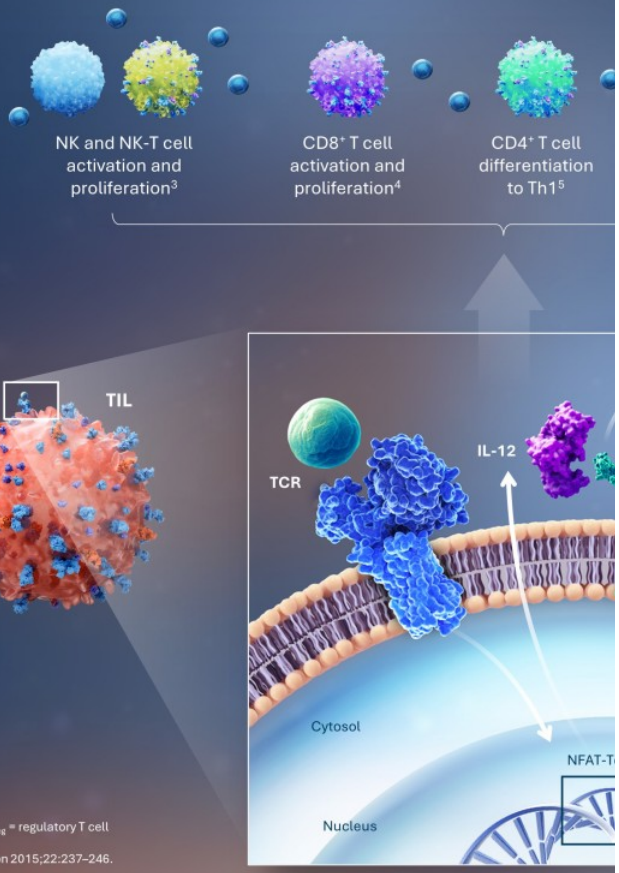
- IOV-3001 is a recombinant fusion protein in which a modified copy of the coding sequence for aldesleukin (mdIL-2) is incorporated into a humanized monoclonal immunoglobulin (Ig)G1κ antibody
- The mdIL-2 moiety of IOV-3001 binds to the IL-2-receptor (IL-2R) with subsequent phosphorylation of signal transducer and activator of transcription 5 (STAT5), resulting in an enhancement in T cell survival and cellular proliferation



Mitra S, Leonard WJ, Journal of Leukocyte Biology 2018 103(4): 643-655
Simpson-Abelson MR, Johnson S et al, ASCO 2024.

IOV-5001 - IL-12 TIL Therapy to Increase Efficacy

- Tethered IL-12 TILs can improve efficacy by remodeling the suppressive tumor microenvironment into an immuno-supportive state
  - In advanced melanoma patients, an ORR of 63% (n=16) was observed using IL-12 TIL doses 10- to 100-fold lower than current TIL products[1]
- IL-12 shows independent clinical efficacy over many modes of administration,[1,2] with safe delivery to the tumor being the primary challenge
- Expression of IL-12 by IOV-5001 is induced upon antigen encounter in the tumor microenvironment[1,2]
- IOV-5001's expressed IL-12 is tethered on the membrane surface of TIL to avoid release into circulation[2]
- Avoidance of IL-12 shedding is expected to allow increased cells doses with IOV-5001 for better persistence, and improved TIL efficacy for use in solid tumor cancers



IL=12 = interleukin 12; MDSC = myeloid derived suppressor cell; NK = natural killer cell; NKT = natural killer T cell; ORR = objective response rate; T_{reg} = regulatory T cell

1. Zhang L, Rosenberg SA, et al, Clin Cancer Res 2015;21(10):2278–2288
2. Zhang L, Davis JS, et al, J Immunother Cancer 2020;8:e000210
3. Kobayashi M, Fitz L, et al, J Exp Med 1989;170:827–845.
4. Zeh HJ, Hurd S et al, J Immunother 1993;14:155–61.
5. Tugues S, Burkhard SH, et al, Cell Death and Differentiation 2015;22:237–246.
6. Cao X, Leonard K, et al, Cancer Res 2009;69:8700–9.
7. Steding CE, Wu S, et al, Immunology 2011;133:221–38.

Corporate Summary & Milestones

Well-Capitalized in Pursuit of TIL Commercialization

June 30, 2024	(in millions)
Unaudited cash position (July 24, 2024)	~$449.6[1]
Common shares outstanding	297.3
Preferred shares outstanding	2.9[2]
Stock options and restricted stock units outstanding	30.7

Cash runway is sufficient into early 2026[3]

1. Includes net proceeds of approximately $200.0 million raised from an at-the market (ATM) equity financing facility during the second and third quarter of 2024
2. Preferred shares are shown on an as-converted basis
3. Includes anticipated revenue from Amtagvi™ and Proleukin®

Anticipated 2024 Milestones

REGULATORY	☑ Obtain FDA approval for lifileucel in advanced melanoma (approved on Feb. 16, 2024)
	☑ Submit EMA regulatory dossier (1H24)
	☐ Submit additional ex-U.S. dossiers (2H24)
	☐ Meet with FDA to discuss NSCLC registrational path/frontline study
PIPELINE	☑ Report clinical and pre-clinical data
	☑ Resume enrollment in IOV-LUN-202
	☑ Initiate Phase 2 trial in endometrial cancer
	☐ Continue to enroll patients in clinical trials for advanced melanoma, NSCLC and gynecological cancers
	☐ Advance new products toward clinic, including additional genetically-modified TIL therapies
MANUFACTURING	☐ Fulfill patient demand for commercial launch and clinical trials
	☐ Further expand capacity to meet U.S. and ex-U.S. demand
COMMERCIAL	☑ Execute commercial launch (1Q24)
	☑ On-board 50 ATCs within 90 days of PDUFA date
	☐ On-board 70 ATCs by end of 2024

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

Corporate Highlights

Pioneering a Transformational Approach to Cure Cancer

Large Market Opportunity in High Unmet Need Cancers

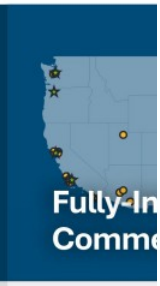
- Initial focus in post-ICI solid tumors
- Expansion into combinations, new tumor types, earlier lines of therapy and genetic modifications
- Key late-stage trials in melanoma, NSCLC
- First-in-human trial of genetically modified PD-1 inactivated TIL

First FDA Approved T Cell Therapy for a Solid Tumor Cancer

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

Efficient and Scalable Proprietary Manufacturing Facility

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



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Abbreviations: FTD, fast track designation; ICI, immune checkpoint inhibitor; NSCLC, non-small cell lung cancer; PD-1, programmed cell death protein-1