

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 9, 2026

IOVANCE BIOTHERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State of Incorporation)

001-36860
Commission File Number

75-3254381
(I.R.S. Employer Identification No.)

825 Industrial Road, Suite 100
San Carlos, California
(Address of Principal Executive Offices)

94070
(Zip Code)

(650) 260-7120
(Registrant's Telephone Number, Including Area Code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.000041666 per value	IOVA	The Nasdaq Stock Market, LLC

Item 8.01 Other Events.

On January 9, 2026, Iovance Biotherapeutics, Inc. (the “Company”) updated its corporate presentation that it uses for presentations at healthcare conferences and to analysts, current stockholders, and others. The Company’s presentation states that the Company expects to achieve its previously disclosed full-year 2025 revenue guidance range of \$250 to \$300 million in the first full calendar year of Amtagvi sales. 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 – January 2026
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 9, 2026

Iovance Biotherapeutics, Inc.

By: /s/ Frederick G. Vogt

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

Title: Interim CEO, President, and General Counsel

IOVANCE

BIO THERAPEUTICS

Corporate Overview

January 2026

ADVANCING IMMUNO-ONCOLOGY

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Forward-Looking Statements

Certain matters discussed in this presentation are “forward-looking statements” of Iovance Biotherapeutics, Inc. (hereinafter referred to as the “Company,” “we,” “us,” or “our”) within the meaning of the Private Securities Litigation Reform Act of 1995 (the “PSLRA”). Without limiting the foregoing, we may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “forecast,” “guidance,” “outlook,” “may,” “can,” “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 trends, current conditions, expected future developments, and other factors believed to be appropriate. Forward-looking statements in this presentation are made as of the date of this presentation, 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 results, levels of activity, performance, achievements, and developments to be materially different from those expressed in or implied by these forward-looking statements. Important factors that could cause actual results, developments, 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 Exchange Commission, 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 unknown risks and uncertainties inherent in our business: the risks related to our ability to successfully commercialize our products; the acceptance by the market of our products and product candidates, if approved, and their potential pricing and/or reimbursement by payors and whether such acceptance is sufficient to support continued commercialization or development of our products or product candidates; the risk regarding our ability to manufacture our therapies using third party manufacturers or at our own facility, including our ability to increase manufacturing capacity at such third party manufacturers and our own facility, may adversely affect our commercial launch; the risk that the successful development or commercialization of our products may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; the risks related to the timing of and our ability to successfully develop, submit, obtain, or maintain regulatory authority approval of our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with regulatory authorities may support registrational studies and subsequent approvals by regulatory authorities; preliminary and interim clinical results, including the interim results for the IOV-LUN-202 trial, which may 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 trials or in other prior trials or cohorts; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities; 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 or renewal of authorization; 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 able to recognize revenue 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 financial performance, including our financial guidance and projections; the effects of global and domestic geopolitical factors or public health events; 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

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Approved Products

AMTAGVI
(lifileucel)

U.S. & Canada

PROLEUKIN
(aldesleukin)

Multiple Markets Globally

>1,000

Patients treated with commercial and clinical Iovance TIL products

Commercial Launch

~95% Addressable Patients within 200 miles of an ATC

>85 Treatment Centers as of 12/31/25*

~\$340M Total Revenue since Launch (as of 9/30/25)¹

Financials

FY25 Revenue Guidance
\$250M - \$300M
(Expect to Achieve)

~\$307M
Cash as of 9/30/25

43%
Gross Margin (Q3 2025)

1. Includes Amtagvi & Proleukin revenue since first infusions following approval (quarters ended 6/30/24-9/30/25)
*Includes centers in final stages of readiness or soon to be authorized.
Abbreviations: FDA=U.S. Food and Drug Administration

The Pioneer in One-Time Cell Therapy for Solid Tumors

First and Only Approved Treatment Regimen in 2L+ Advanced Melanoma

AMTAGVI¹
(lifileucel)

PROLEUKIN²

- **\$1B+ peak sales potential**
- Long-term durability: a third of responses ongoing; ~20% OS; mDOR of >36 months at 5 years¹
- **FY25 revenue anticipated within guidance range (\$250-\$300M)**
- ~50% response in real world patients improves upon clinical experience²

Lifileucel in 2L mNSCLC

- High unmet need with few treatment options and limited durability with SOC
- **~7X current melanoma commercial opportunity**
- Unprecedented durability in difficult-to-treat 2L mNSCLC population³
- Completion of enrollment and data update expected in 2026 with potential launch in 2H27
- Leverages current melanoma manufacturing and commercial strength

Organizational Strength

- **\$307M cash⁴ expected to fund operations into 2Q27**
- **Organization streamlined starting in 3Q25**, and ongoing, supporting improved margins
- Modular manufacturing facility for economies of scale
- Global portfolio rights
- Global field teams
- Global supply chain and logistics

1. Medina et al, ASCO 2025, Pooled Analysis (n=153), Heavily Pre-Treated Patient Population

2. Physician-assessed CRR. All evaluable patients received commercial Amtagvi according to the U.S. prescribing information and completed at least one follow-up physician assessment. Data on file.

3. Interim data cut as of October 10, 2025 of patients with nonsquamous NSCLC with minimum cell dose based on FDA feedback. Patients progressed on or after chemotherapy and anti-PD-1 therapy for mNSCLC without EGFR, ROS1 or ALK genomic mutations and received at least one line of FDA-approved targeted therapy if indicated by other actionable tumor mutations

4. As of September 30, 2025

Abbreviations: 2L=second line; mDOR=median duration of response; mNSCLC=metastatic non-small cell lung cancer; OS=overall survival; SOC=standard of care

Iovance Solid Tumor Portfolio Highlights

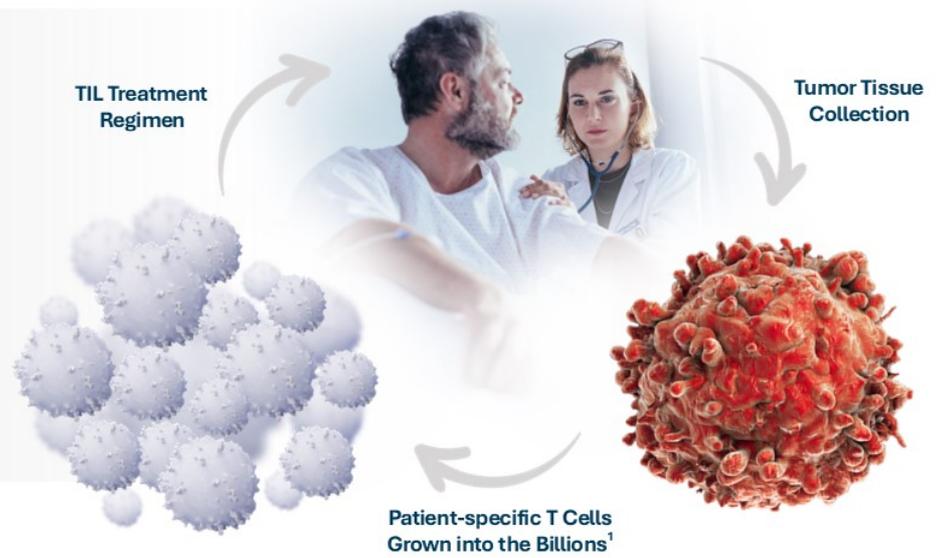
	INDICATION & TREATMENT SETTING	PHASE 1	PHASE 2	PHASE 3	APPROVED
Commercial	 AMTAGVI (lifileucel)	Post-anti-PD-1 advanced melanoma (U.S., Canada) UK, Australia & Switzerland submitted		[Phase 1/2/3/Approved]	
	 PROLEUKIN (lifileucel)	Amtagvi treatment regimen (U.S., Canada) Advanced melanoma, renal cell carcinoma (U.S., ex-U.S.)		[Phase 1/2/3/Approved]	
Label Expansion Opportunities	Registration-Directed	Lifileucel + pembrolizumab	Frontline advanced melanoma	TILVANCE-301 (FTD, Confirmatory)	
		Lifileucel	Post-chemo & anti-PD-1 advanced NSCLC	IOV-LUN-202: Cohorts 1&2	
		Lifileucel	Post anti-PD-1 advanced melanoma	IOV-MEL-202	
	Lifileucel Pipeline	Lifileucel	Post-chemo & anti-PD-1 endometrial cancer	IOV-END-201: Cohorts 1&2	
		Lifileucel; + ICI; +ICI & chemo	1-4L ICI-naïve & post-anti-PD-1 advanced NSCLC	IOV-COM-202: Cohorts 3A-3E*	
		Lifileucel + ICI	ICI-naïve advanced melanoma	IOV-COM-202: Cohorts 1A, 1D*	
Next-Generation Products	PD-1 Inactivated TIL (IOV-4001)	Post anti-PD-1 advanced melanoma	IOV-GM1-201: Cohort 1		
	PD-1 Inactivated TIL (IOV-4001)	2-4L incl. post-anti-PD-1 advanced NSCLC	IOV-GM1-201: Cohort 2		
	IL-2 analog (IOV-3001)	TIL treatment regimen	IOV-IL2-101		
	IL-12 tethered TIL (IOV-5001)	Basket trial	Planned		

*Enrollment complete in IOV-COM-202 Cohorts 1A, 3A, 3B, 3C; Cohorts 1D, 3D & 3E not yet enrolling.
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

Unique Mechanism of Action

- Individualized
- One-time therapy
- Patient's T cells fight cancer



1. Amtagvi USPI

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Market Expansion Opportunity in Solid Tumors

91% of all cancer cases are solid tumors¹

1 New indications:

	U.S. Deaths ¹	Global Deaths ²
Melanoma	8K	59K
Lung & Bronchus	125K	1.8M
Endometrial	13K	97K

2 Additional markets:



1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2025 Estimates. <https://seer.cancer.gov> (accessed August 2025)
2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022

AMTAGVI[™]
(lifileucel) Suspension
for IV infusion

First FDA-approved One-time, Individualized T cell Therapy for a Solid Tumor Cancer

Advanced Melanoma Market Opportunity

Significant unmet need in frontline and beyond¹

2L+ Advanced
Melanoma Population^{2,3}

US:
8K

Potential
ex-US Markets:
22K

Overall (1L+):
70K

>50% of patients on 1L standard of care progress within 12 months⁴⁻⁶

mOS after
Progression on
1L Therapy⁷:

~5 months

BRAF wild-type
(prior ICI therapy)

~3 months

BRAF mutated
(prior ICI and targeted therapy)

Abbreviations: 1L, first line; ICI, immune checkpoint inhibitors; mOS, median overall survival; mPFS, median progression-free survival; PD (L)1, programmed death receptor 1 or programmed death-ligand 1; Chenoy J, et al. *J Immunother Cancer* 2022; 2. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program, 2020 Estimates. <http://seer.cancer.gov/> (accessed August 2023); World Health Organization International Agency for Research on Cancer (IARC). *GLOBALCAN 2022-3*. Data on file as of July 2022. Includes more than 20,000 patients initial target markets plus additional potential markets; 4. Larkin J, Chiarion-Soto A, Gonzalez R, et al. *NEJM*. 5. Robert C, et al. *Lancet*. 6. Tawbi HA, Schadendorf D, Lipson EJ, et al. *NEJM*. 7. Pattniroy J, et al. *Cancer* 2020

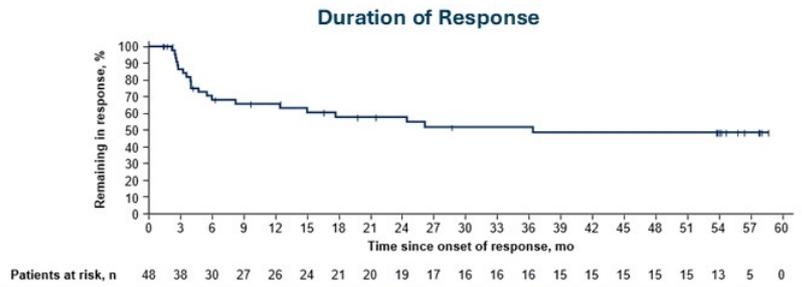
Deep and Durable Responses at 5-Year Follow Up¹

One Third of Responses Remain Ongoing without Subsequent Treatment

ORR
31.4%

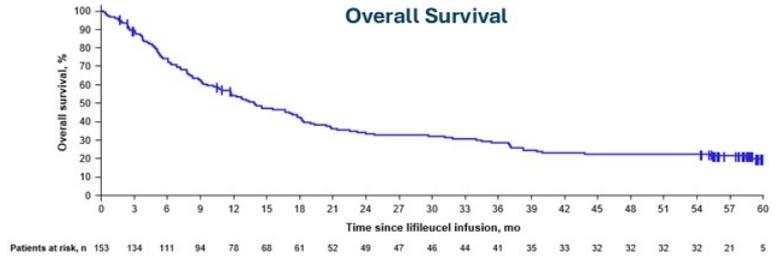
mDOR
36.5 Months

Median Follow Up
57.8 Months



5 Year OS
19.7%

mOS
13.9 Months



¹ Medina et al, ASCO 2025. Pooled Analysis (n=153), Heavily Pre-Treated Patient Population
Abbreviations: mDOR=median duration of response; mOS=median overall survival; NR=not reached; ORR=objective response rate; OS=overall survival

~50% Response Rate in Preliminary Real-World Analysis¹

Additional Data to be Presented at Tandem Meetings 2026

48.8% ORR (20/41)

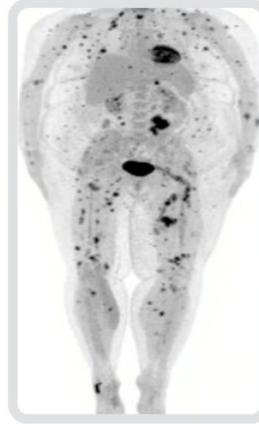
Higher ORR with earlier treatment

60.9% ORR (14/23)
≤ 2 prior lines of therapy

33.3% ORR (6/18)
≥ 3 prior lines of therapy

Durable Ongoing Partial Response (PR)²
Significant tumor burden reduction at Week 6

Before Lifileucel



Post-Lifileucel (Week 6)



1. Physician-assessed ORR. All evaluable patients received commercial Amtagvi according to the U.S. prescribing information and completed at least one follow-up physician assessment. Data on file.
2. Three Prior Lines of Therapy (1L-3L): 1L: ipilimumab + nivolumab; 2L: dabrafenib + trametinib; 3L: nivolumab + relatlimab. 86% reduction in target lesions. Response ongoing at 260-day follow-up. Photo Credit and Permission: H. Lee Moffitt Cancer Center
Abbreviations: ORR-objective response rate

Amtagvi® Patient Journey

Broad payer coverage consistent with Amtagvi label, clinical trials and NCCN guidelines



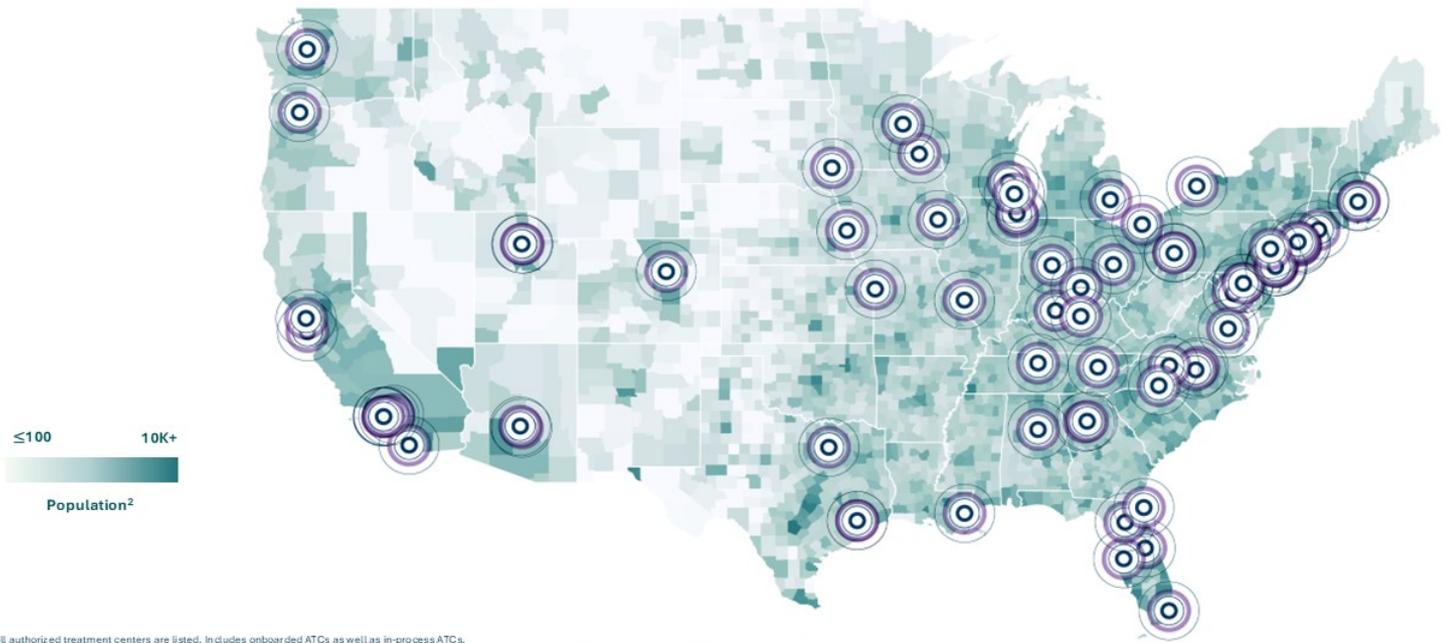
Manufacturing Facility Dedicated to Commercial and Clinical TIL Cell Therapies

- Modular design
- Global supply and logistics
- Capacity for up to 5K patients/year
- Optimal utilization, quality & COS



COS = cost of sales

Amtagvi® Authorized Treatment Centers (ATC)



1. Not all authorized treatment centers are listed. Includes onboarded ATCs as well as in-process ATCs.
2. U.S. Census Bureau, 2024 Annual Estimates. SEER annual estimated death rate from melanoma: 2 deaths per 100K people; <https://seer.cancer.gov/> (accessed April 2025)
3. Internal data

Broad Market Access

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



Data on file as of July 2025.
*Plans or policies that cover Amtagvi, including pharmacy benefit managers (PBMs)
Abbreviations: NCCN = National Comprehensive Cancer Network

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Amtagvi® Expansion Plans in Advanced Melanoma



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

Data support rationale for TILVANCE frontline study:¹

65.2%

ORR via RECIST v 1.1

30.4%

CR

64.7%

PFS at 6 & 12 months

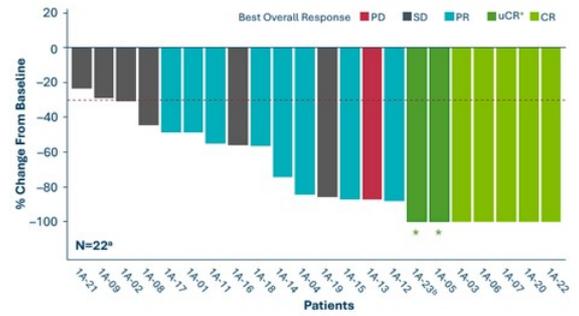
- Median PFS and median DOR not reached at nearly 2 years of median follow-up (median follow-up 21.7 months)
- All response-evaluable patients demonstrated regression of target lesions
- Safety consistent with underlying disease and known safety profiles of pembrolizumab, NMA-LD, lifileucel, and IL-2
- Late AEs consistent with anti-PD-1 monotherapy, differentiated from ICI combination therapies

1. Thomas et al, ASCO 2024; Data on file as of May 31, 2024.

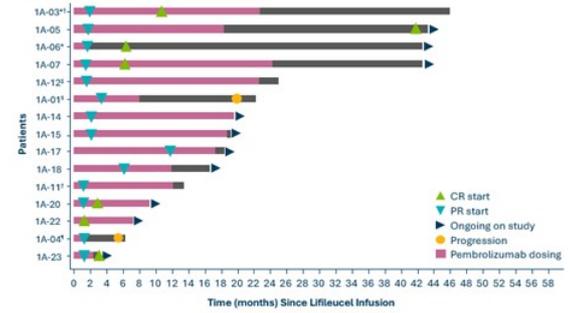
* Unconfirmed CRs, confirmed following data cut.

^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; DOR, duration of response; ICI, immune checkpoint inhibitor; ORR, objective response rate; PD, progressive disease; PFS, progression free survival; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SOD, sum of diameter; AE, adverse event; IL-2, interleukin-2; NMA-LD, nonmyeloablative lymphodepletion

Best Percentage Change from Baseline in Target Lesion SOD

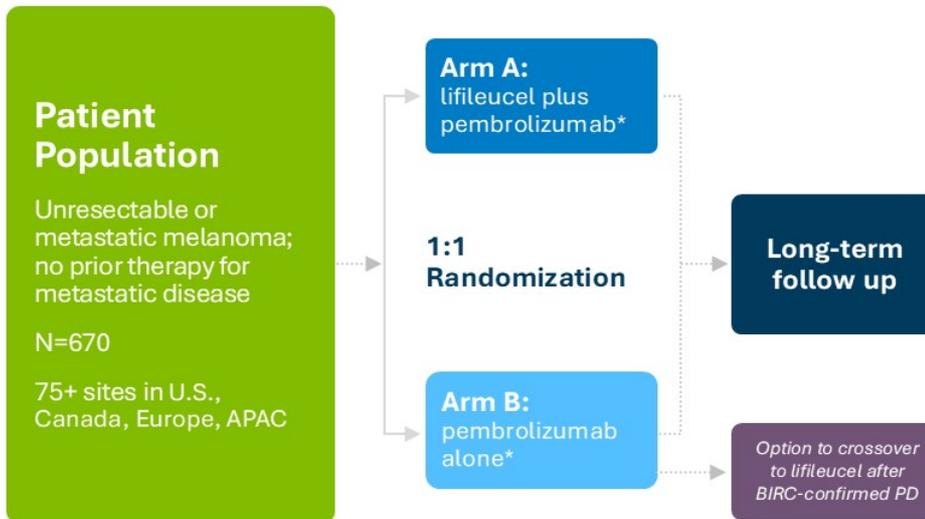


Time to Response and Time of Efficacy Assessment for Confirmed Responders (PR or Better)



TILVANCE-301 Global Phase 3 and Confirmatory Trial

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



Study Design with FDA Agreement

- Dual primary endpoints: ORR & PFS
- Interim analysis on ORR
- Final analysis on PFS
- Registrational for frontline melanoma
- Confirmatory for full approval of Amtagvi® in post-anti-PD-1 melanoma
- Enrollment on track with internal projections

*Pembrolizumab in both arms is started at the same time after randomization.

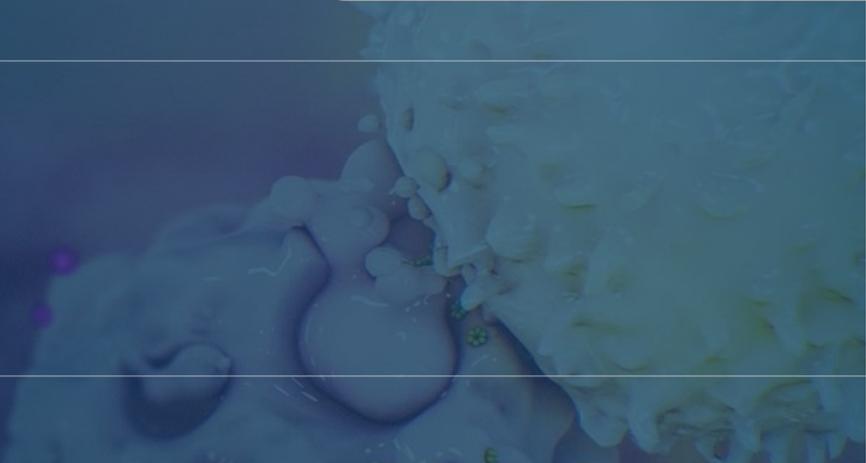
Abbreviations: BIRC=blinded independent review committee; ORR=objective response rate; PD=progressive disease; PD-1=programmed cell death protein-1; PFS=progression free survival

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TIL Therapy Pipeline

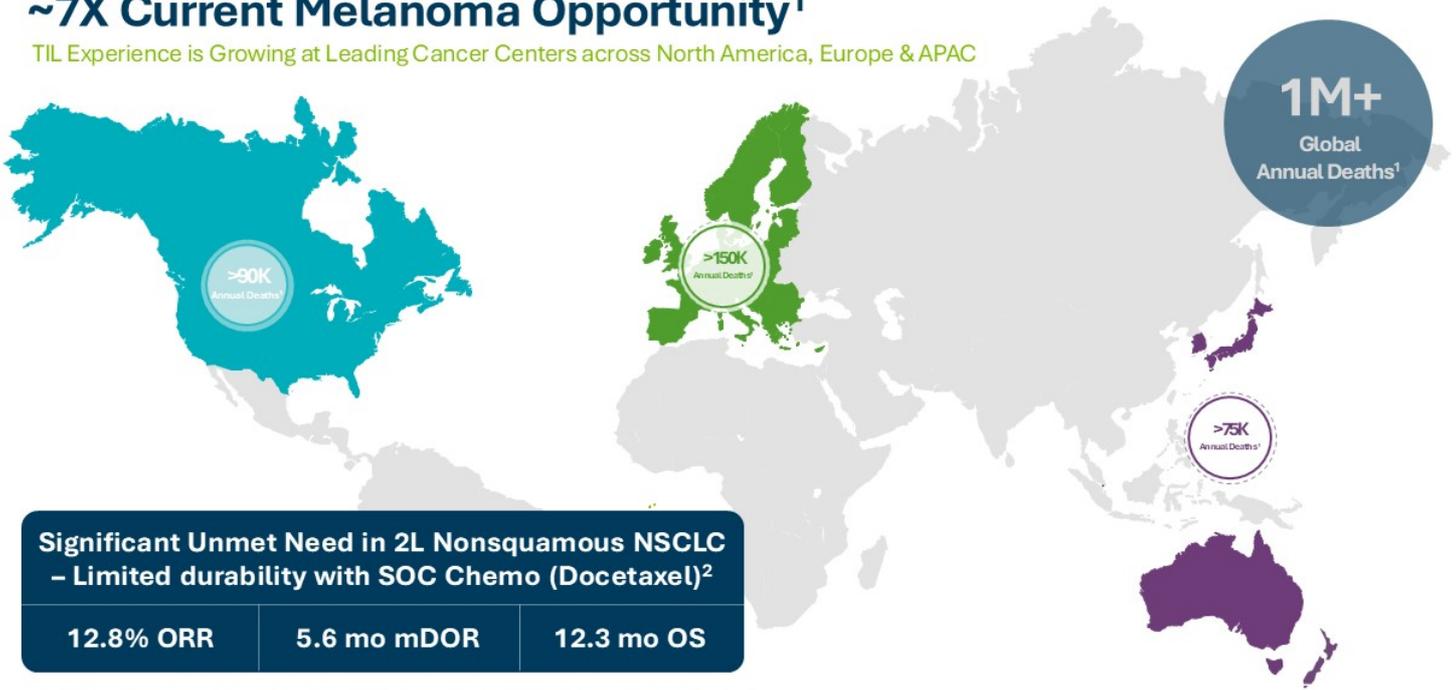


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Global NSCLC Commercial Opportunity ~7X Current Melanoma Opportunity¹

TIL Experience is Growing at Leading Cancer Centers across North America, Europe & APAC



**Significant Unmet Need in 2L Nonsquamous NSCLC
– Limited durability with SOC Chemo (Docetaxel)²**

12.8% ORR

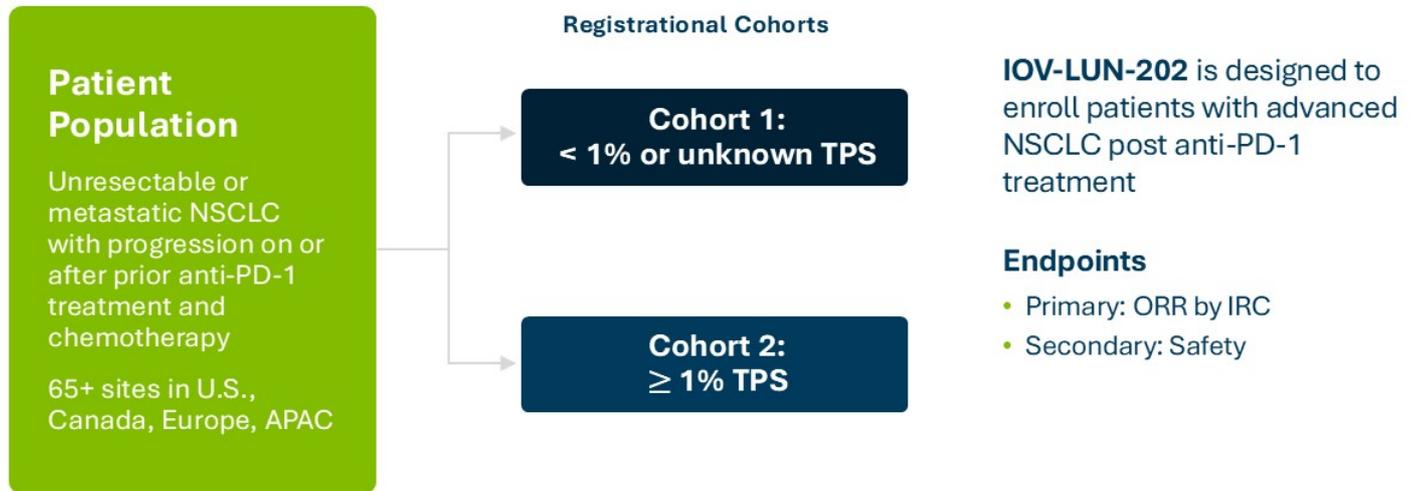
5.6 mo mDOR

12.3 mo OS

1. Data on file as of November 2025, includes targeted patient population in potential future commercial markets. 2. Ahn MJ et al. J Clin Onc 2024;43:260-272. Abbreviations: APAC, Asia Pacific; mDOR, median duration of response; mo, month; NSCLC, non-small-cell lung cancer; ORR, objective response rate; OS, overall survival; SOC, standard of care

IOV-LUN-202 Registrational Trial Design

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



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

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Clinical Profile in Second-Line Nonsquamous mNSCLC

One-Time Therapy with Unprecedented Durability and Responses Regardless of PD-L1 Status¹

25.6% ORR

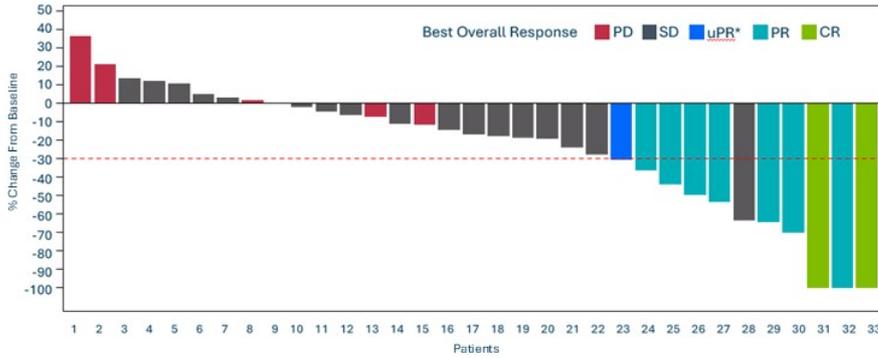
(n=39; RECIST 1.1)



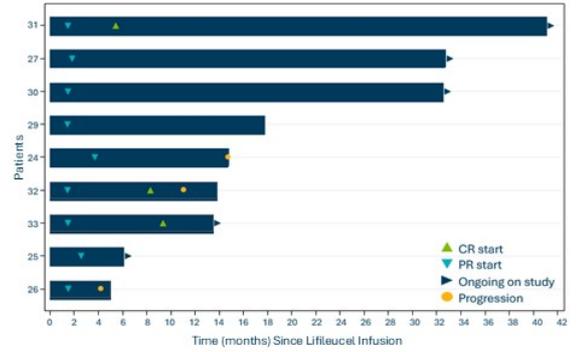
mDOR Not Reached

(Median follow up: 25.4 months)

Best Percentage Change from Baseline in Target Lesion(s)



Durability of Response²



¹Interim data cut as of October 10, 2025 of patients with nonsquamous NSCLC with minimum cell dose based on FDA feedback. Patients progressed on or after chemotherapy and anti-PD-1 therapy for mNSCLC without EGFR, ROS1 or ALK genomic mutations and received at least one line of FDA-approved targeted therapy if indicated by other actionable tumor mutations. ²Time to response, time on assessment for confirmed responders (PR or better). A bar is presented for each patient starting from date of lifleucel infusion up to date of new anti-cancer therapy, end of assessment, death, or data cutoff date, whichever occurs earlier. *Patient 23 in ongoing follow up to confirm PR. CR=complete response; mNSCLC=metastatic non-small cell lung cancer; ORR=objective response rate; PD=progressive disease; PR=partial response; RECIST=Response Evaluation Criteria in Solid Tumors; SD=stable disease; uPR=unconfirmed partial response.

Cohort 3A Results Support Adding TIL Therapy to Frontline NSCLC¹

PD-L1 negative, EGFR^{WT} subgroup has a high unmet need²

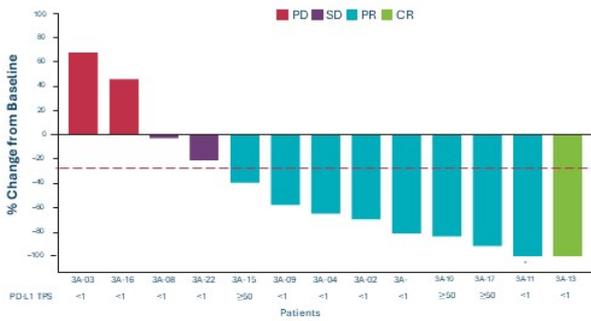
64.3% ORR EGFR^{WT}

↳ **54.5% ORR** EGFR^{WT} PD-L1 Negative
by RECIST 1.1

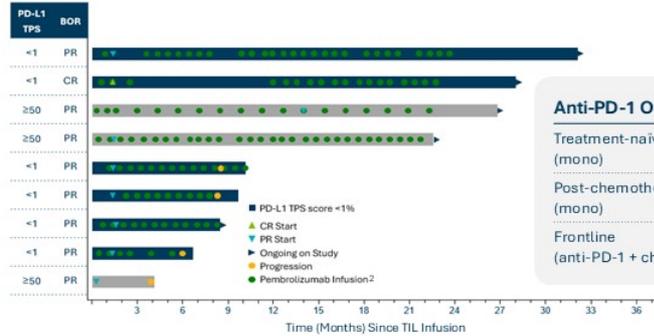
mDOR not reached (median follow-up 26.5 months)

- Safety consistent with lovance TIL combination studies
- Supports adding TIL therapy to pembrolizumab plus chemotherapy for frontline NSCLC in IOV-COM-202 cohorts 3D/3E

Best Percentage Change from Baseline in Target Lesion SOD



Time to Response for Confirmed Responders (PR or Better, EGFR^{WT} Patients)



Anti-PD-1 ORR Benchmarks²

Treatment-naïve (mono)	27% (TPS ≥ 1%); 39 - 45% (TPS ≥ 50%)
Post-chemotherapy (mono)	18 - 20%
Frontline (anti-PD-1 + chemo)	48-58%

1. Creelan et al. JTO 2024

2. KEYTRUDA USP; OPDIVO USP

*PR response based on target lesion reduction of 100% with the persistence of nontarget lesions.

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

Potential Market for Advanced Endometrial Cancer

Immunosensitive Tumor Type with Significant Unmet Need in 2L+

Endometrial
Cancer
Biomarkers⁴

dMMR: 27%
pMMR: 73%

>90%
of Uterine Cancers
are Endometrial

~14K US annual uterine
cancer deaths¹

~98K Global deaths²

19.5% 5-yr survival
(distant metastases)¹

Anti-PD-(L)1 moving into front-line
therapy setting³

No standard of care 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%^{5,6}
- Limited data on treatments after anti-PD-(L)1

1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2025 Estimates. <https://seer.cancer.gov> (accessed August 2025); 2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022; 3. NCCN Guidelines Version 2.2024 Endometrial Carcinoma; 4. Kang et al, Nature Portfolio, Scientific Reports, 2022; 5. Makker V, et al. N Engl J Med. 2022; 6. 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; SOC=standard of care; TMB-H = tumor mutational burden high; ORR = objective response rate

IOV-END-201 Phase 2 Proof of Concept Study

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

Endometrial Cancer Patient Population*

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

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

pMMR Subgroup

dMMR Subgroup

Endpoints

- **Primary:** ORR per RECIST v1.1 by investigator
- **Secondary:** CR rate, DOR, DCR, PFS, OS, safety and tolerability
- Subgroup analyses specified in protocol
- Potential to expand / convert to registrational trial
- First patient enrolled Q4 2024

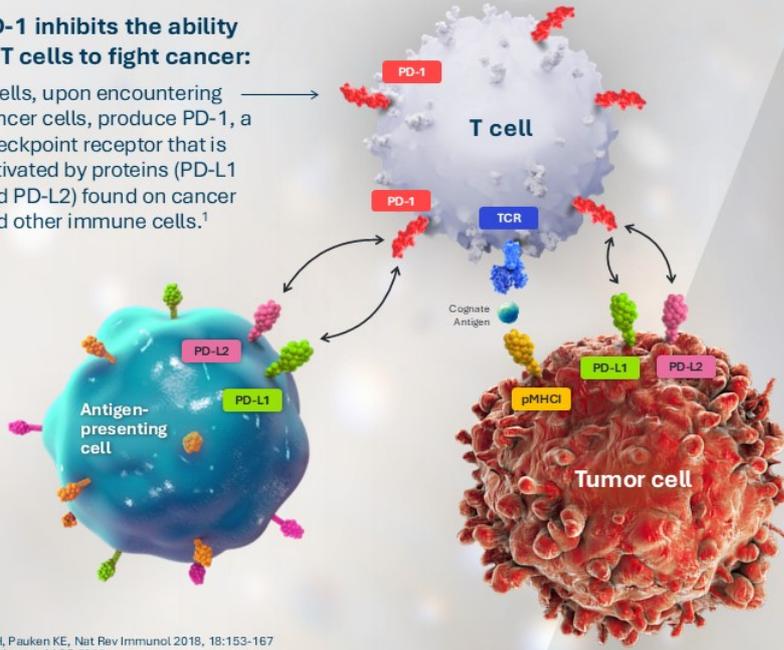
*Sample size and study population of registrational ph2 study will be determined after PoC final analysis

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

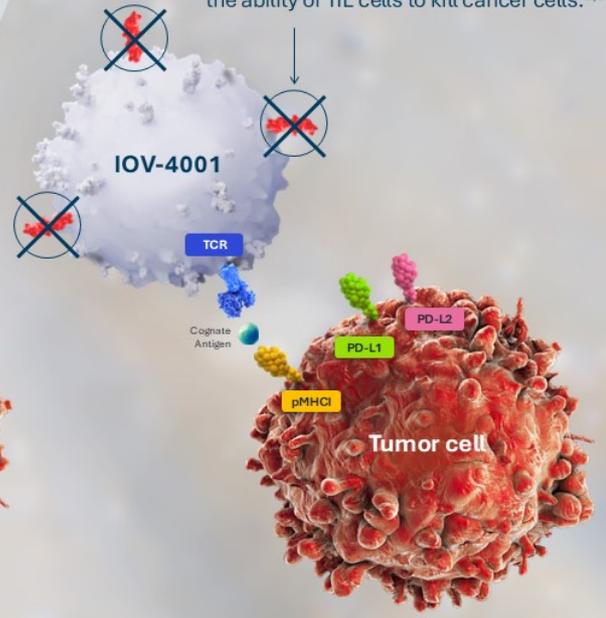
1 PD-1 inhibits the ability of T cells to fight cancer:

T cells, upon encountering cancer cells, produce PD-1, a checkpoint receptor that is activated by proteins (PD-L1 and PD-L2) found on cancer and other immune cells.¹



2 PD-1 Inactivated T Cells Avoid Checkpoint Signals:

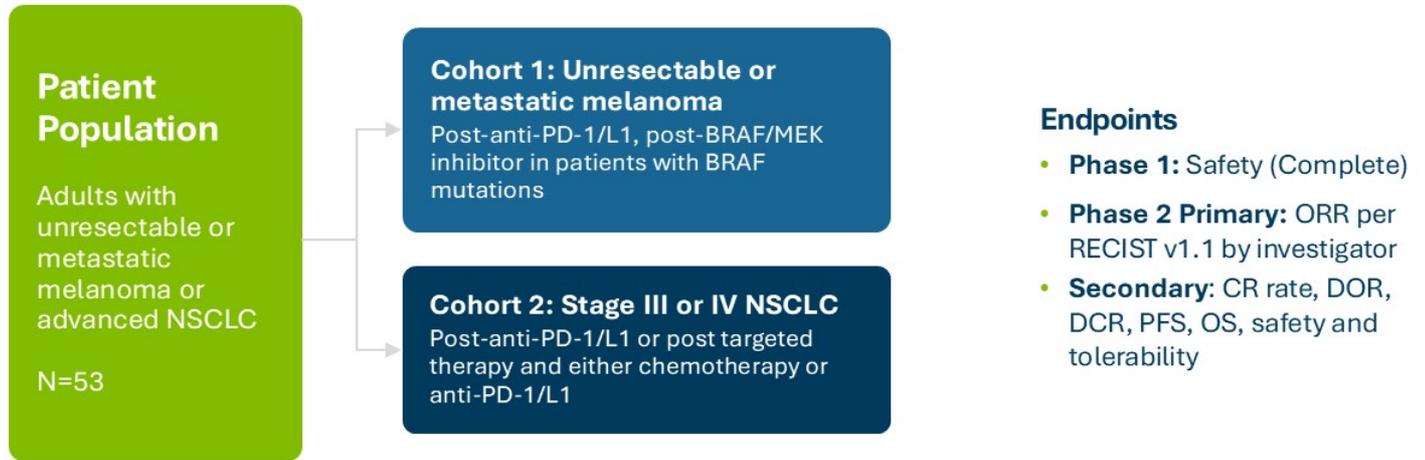
PD-1 is inactivated using TALEN, restoring the ability of TIL cells to kill cancer cells.^{2,3}



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

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 NSCLC (NCT05361174)



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

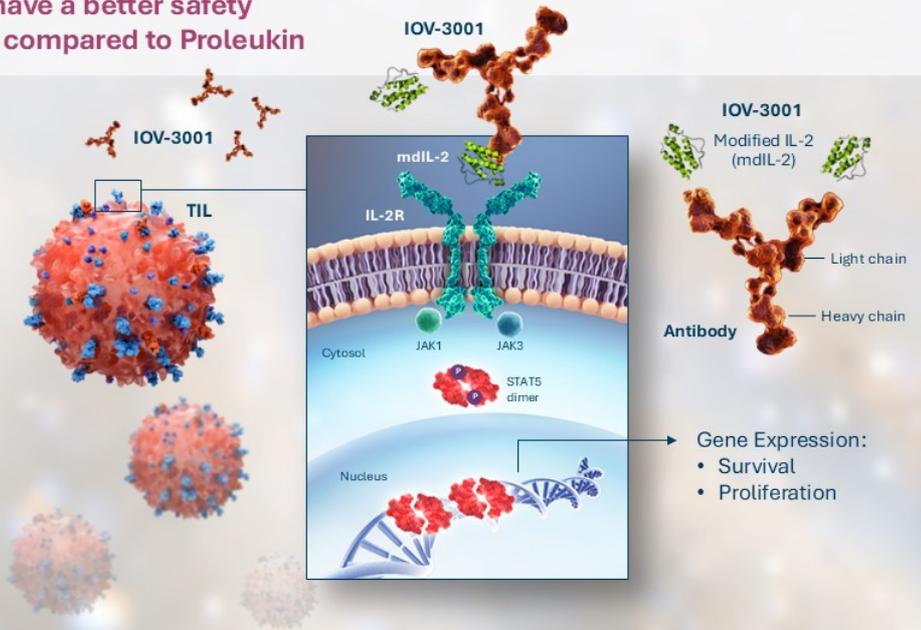
IOV-3001: Next Generation IL-2 for TIL Supportive Regimen^{1,2}

Preclinical data suggest IOV-3001 may have a better safety profile and require less frequent dosing compared to Proleukin

Phase 1/2 trial enrolling patients

Recombinant fusion protein designed to enhance TIL survival and cellular proliferation

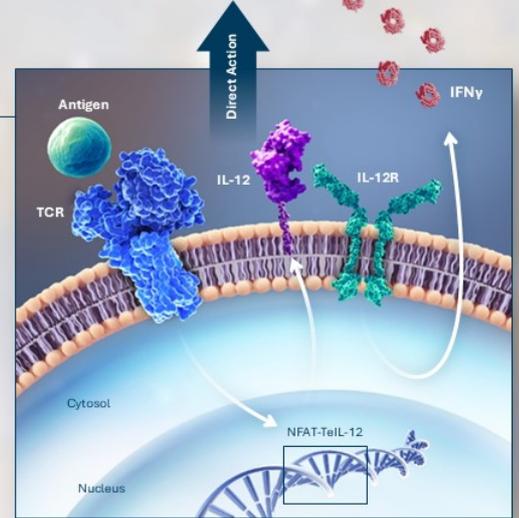
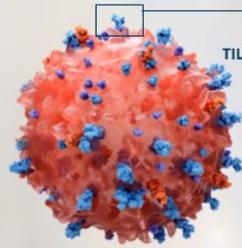
- A modified copy of the coding sequence for aldesleukin (mdIL-2) is fused to a humanized monoclonal immunoglobulin (Ig)G1κ antibody
- The mdIL-2 moiety of IOV-3001 binds to the IL-2-receptor (IL-2R) with subsequent phosphorylation of signal transducer and activator of transcription 5 (STAT5), resulting in enhanced performance



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

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

- Tethered IL-12 TIL cells can improve efficacy by remodeling the suppressive TME into an immunosupportive state
 - In advanced melanoma patients, an ORR of 63% (n=16) was observed with prior generation IL-12 secreting TIL product at doses 10- to 100-fold lower than conventional TIL products¹
- IL-12 shows independent clinical efficacy, with safe delivery to the TME being the primary challenge^{1,2}
- Expression of IL-12 on IOV-5001 is induced upon antigen encounter in the TME^{1,2}
- IOV-5001's expressed IL-12 is tethered to the membrane surface of TIL to avoid release into circulation (shedding)²
- Inducible IL-12 expression in the TME and lack of IL-12 shedding are expected to allow increased IOV-5001 cell doses and improved TIL efficacy in solid tumor cancers



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. Zehn H, Hurd S et al, J Immunother 1993;14:155-61.

IL-12 = interleukin 12; MDSC = myeloid derived suppressor cell; NK = natural killer cell; NKT = natural killer T cell; ORR = objective response rate; TME = tumor microenvironment; Treg = regulatory T cell

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



Financial Position & Outlook

Guidance

Cash runway into

Q2 2027¹

FY 2025 revenue

\$250M - \$300M

**Revenue Growth
Margin Improvement
Cost Control**

September 30, 2025

(in millions)

Cash position	\$306.8
Common shares outstanding	385.5
Preferred shares outstanding	2.0 ²
Stock options and restricted stock units outstanding	28.5

1. Includes anticipated revenue from Amtagy[®] and Proteukin[®] and anticipated savings from strategic restructuring announced on August 7, 2025
2. Preferred shares are shown on an as-converted basis.



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Thank You

ADVANCING IMMUNO-ONCOLOGY

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