

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
Current Report

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): February 24, 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 share	IOVA	The Nasdaq Stock Market LLC

Item 2.02 Results of Operations and Financial Condition.

On February 24, 2026, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2025, and an update on recent developments. A copy of that press release is furnished as Exhibit 99.1.

The information furnished under this Item 2.02, including the accompanying Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of such section, nor shall such information be deemed to be incorporated by reference in any subsequent filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language of such filing, except as specifically stated in such filing.

Item 8.01 Other Events.

On February 24, 2026, the Company updated its corporate presentation that it uses for presentations at healthcare conferences and to analysts, current stockholders, and others. A copy of the Company's presentation that it intends to use at such events is attached as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Iovance Biotherapeutics, Inc., dated February 24, 2026.
99.2	Iovance Biotherapeutics, Inc., Corporate Presentation - February 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.

Dated: February 24, 2026

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 Highlights Strong Fourth Quarter and Full Year 2025
Results, Business Achievements and Corporate Updates**

~30% Quarterly Revenue Growth Driven by Amtagvi Demand

Gross Margin Increased to 50%

FY25 Revenue of \$264M Achieved Annual Guidance

*U.S. FDA Fast Track Designation Granted for Lifileucel in
Second-Line Advanced Non-Small Cell Lung Cancer*

SAN CARLOS, Calif., February 24, 2026 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a commercial biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today reported fourth quarter and full year 2025 financial results, business achievements and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "Iovance delivered approximately 30 percent quarterly revenue growth and achieved our 2025 guidance range in the first full calendar year of launch. Growth was driven by increasing demand for Amtagvi. After ongoing improvements in our operations and gross margin, we are well positioned for future profitability. Iovance is poised to create substantial value for patients and shareholders as we increase revenue while advancing our registrational trial in non-small cell lung cancer and best-in-class TIL pipeline in solid tumors."

Fourth Quarter and Full Year 2025 Financial Highlights

Topline Growth, Significant Margin Improvement, and Cost Optimization

- Fourth quarter 2025 total product revenue of ~\$87 million with strong growth of ~30% over the prior quarter, including:
 - o U.S. Amtagvi revenue of ~\$65 million.
 - o Global Proleukin revenue of ~\$22 million.
 - Fourth quarter 2025 gross margin from cost of sales was ~50%, reflecting increasing benefits from solid execution and cost optimization.
 - Full year 2025 total product revenue of ~\$264 million achieved the guidance range of \$250 million to \$300 million in the first full year of launch, including:
 - o U.S. Amtagvi revenue of ~\$220 million.
 - o Global Proleukin revenue of ~\$44 million.
 - The cash position as of December 31, 2025 of ~\$303 million¹ is expected to fund operations into the third quarter of 2027.
 - Operational excellence initiatives, including internalization of all lifileucel manufacturing and optimization of research and development activities, are expected to drive significant additional improvements in operating expenses, cost of sales and gross margin in 2026 and 2027.
-

Amtagvi Commercial Launch

Strong U.S. Commercial Growth and Execution with Approvals Pending in New Global Markets

- Best-in-class Amtagvi real-world response rates are increasing adoption and strengthening referral trends toward earlier treatment.
 - An [oral presentation](#) at the 2026 Tandem Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT[®]) and the Center for International Blood and Marrow Transplant Research (CIBMTR[®]) reported:
 - An unprecedented overall objective response rate (ORR) of ~44%.
 - Higher ORR of 52% after two or fewer prior lines of therapy, highlighting the importance of early treatment.
- A continuously growing and maturing network of U.S. authorized treatment centers (ATCs) expanded patient access in 2025, with further acceleration anticipated in 2026.
 - Academic ATCs are contributing to growth as new centers onboard and experienced centers treat more patients.
 - The first community ATCs began treating patients in late 2025 and are expected to drive additional demand in 2026.
 - A specialty pharmacy distribution channel was introduced as another option for ATCs to purchase Amtagvi.
- Five-year analysis of the C-144-01 trial of Amtagvi demonstrated ~31% ORR, median duration of response (mDOR) of 36+ months, and ~20% five-year overall survival, highlighting the unprecedented long-term benefits of this first-in-class therapy.
- Manufacturing turnaround improved to 32 days or less from inbound to return shipment to ATCs.
- Global expansion of Amtagvi is underway in several markets outside the U.S.
 - Amtagvi was approved in Canada in August 2025.
 - Regulatory submissions are under review with potential approvals in the United Kingdom and Australia in the first half of 2026, and Switzerland in the first half of 2027.
 - Iovance is working with the European Medicines Agency (EMA) to resubmit a marketing authorization application (MAA) in 2026.

Lifileucel in Previously Treated Advanced NSCLC: IOV-LUN-202 Registrational Trial

Clinical and Regulatory Momentum Building Towards Potential 2H27 Launch

- The U.S. FDA granted Fast Track Designation (FTD) for lifileucel for the treatment of adults with metastatic nonsquamous (NSQ) NSCLC that has progressed on or after chemo- and anti-PD-1 therapies and at least one line of FDA-approved targeted therapy, if indicated, for actionable tumor mutations excluding ALK, ROS1 and EGFR.
 - Positive interim [data](#) demonstrated a potential best-in-class profile in NSQ advanced NSCLC patients.
 - The ORR was 26% and mDOR was not reached at 25+ months of follow up following one-time lifileucel monotherapy.
 - Standard of care docetaxel has shown 12.8% ORR, 5.6 months mDOR, and 12.3 months overall survival, highlighting a significant unmet medical need.²
 - Anticipated milestones:
 - Present updated data at a major medical meeting in 2026.
 - Complete enrollment in 2026.
 - Support a supplemental Biologics License Application for U.S. accelerated approval with a potential launch in the second half of 2027.
-

Pipeline Updates

New Data Across Several Pipeline Programs Anticipated Throughout 2026

- Iovance announced positive early data for one-time lifileucel treatment in patients with advanced undifferentiated pleomorphic sarcoma (UPS) or dedifferentiated liposarcoma (DDLPS) who were refractory to at least one prior line of systemic therapy:
 - o Among the first six evaluable patients, the confirmed RECIST v1.1 ORR was 50%.
 - o Iovance plans to commence a single arm registrational trial in previously treated advanced UPS and DDLPS in the second quarter of 2026 and engage with the FDA on a path to expedited approval.
- The Phase 3 TILVANCE-301 trial of lifileucel and pembrolizumab in frontline advanced melanoma made significant progress, with enrollment accelerating across a broad and expanding global footprint. The U.S. FDA previously granted FTD in frontline advanced melanoma for lifileucel in combination with pembrolizumab. The TILVANCE-301 trial is designed with FDA and EMA input to show contribution of components for lifileucel in combination with pembrolizumab compared to pembrolizumab alone.
- Two of Iovance's Phase 2 trials, IOV-END-201 and IOV-MEL-202, are investigating lifileucel in previously treated patients with advanced endometrial cancer and melanoma, respectively.
- A Phase 1/2 trial is investigating IOV-4001, a PD-1 inactivated TIL therapy, in previously treated advanced melanoma and NSCLC.
- A Phase 1/2 trial is investigating IOV-3001, a second-generation, modified IL-2 analog for use in the TIL treatment regimen.
- An Investigational New Drug (IND) submission is planned in the first half of 2026 to begin clinical development of IOV-5001, a genetically engineered, inducible, and tethered interleukin-12 TIL therapy, in a Phase 1/2 basket trial.
- Multiple investigator-sponsored clinical trials are exploring new solid tumor indications for Iovance TIL therapies and next generation approaches.

Webcast and Conference Call

Management will host a conference call and live audio webcast to discuss these results and provide a corporate update today at 8:30 a.m. ET. To listen to the live or archived audio webcast, please register at <https://edge.media-server.com/mmc/p/5rbo34au>. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com, for one year.

1. Cash, cash equivalents, short-term investments, and restricted cash as of December 31, 2025
 2. Ahn MJ et al. J Clin Onc 2024;43:260-272.
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About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics, Inc. aims to be the global leader in innovating, developing, and delivering tumor infiltrating lymphocyte (TIL) therapies for patients with cancer. We are pioneering a transformational approach to cure cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells in each patient. The [Iovance TIL platform](#) has demonstrated promising clinical data across multiple solid tumors. Iovance's Amtagvi[®] is the first FDA-approved T cell therapy for a solid tumor indication. We are committed to continuous innovation in cell therapy, including gene-edited cell therapy, that may extend and improve life for patients with cancer. For more information, please visit www.iovance.com.

Amtagvi[®] and its accompanying design marks, Proleukin[®], Iovance[®], and IovanceCares[™] are trademarks and registered trademarks of Iovance Biotherapeutics, Inc. or its subsidiaries. All other trademarks and registered trademarks are the property of their respective owners.

Information on Iovance's broad, industry-leading patent portfolio is available on the Intellectual Property page on www.iovance.com.

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 "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 press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as 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 at our iCTC facility, including the risk that our ability to increase manufacturing capacity at our 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, including the risk that the planned registrational trial in advanced sarcomas may not support approval; preliminary and interim clinical results, 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, and other factors such as the number of ATCs, may not 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. Any financial guidance provided in this press release assumes the following: no material change in our ability to manufacture our products; no material change in payor coverage; no material change in revenue recognition policies; no new business development transactions not completed as of the period covered by this press release; and no material fluctuation in exchange rates.

IOVANCE BIOTHERAPEUTICS, INC.
Selected Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2025	December 31, 2024
Cash, cash equivalents, and investments	\$ 296,980	\$ 323,781
Restricted cash	\$ 5,980	\$ 6,359
Total assets	\$ 913,170	\$ 910,426
Stockholders' equity	\$ 698,583	\$ 710,405

Condensed Consolidated Statements of Operations

(in thousands, except per share information)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2025 (unaudited)	2024 (unaudited)	2025	2024
Revenue				
Product revenue, net	\$ 86,771	\$ 73,694	\$ 263,502	\$ 164,070
Total revenue	86,711	73,694	263,502	164,070
Costs and expenses*				
Cost of sales**	\$ 43,112	\$ 37,789	\$ 173,184	\$ 93,248
Research and development**	71,202	71,007	300,270	276,228
Selling, general and administrative**	36,400	42,321	152,322	152,269
Depreciation and amortization	9,517	9,153	35,939	37,603
Restructuring charges	—	—	5,143	—
Total costs and expenses	160,231	160,270	666,858	559,348
Loss from operations	(73,460)	(86,576)	(403,356)	(395,278)
Other income				
Interest and other income, net	1,740	9,575	10,307	20,273
Net Loss before income taxes	(71,720)	(77,001)	(393,049)	(375,005)
Income tax (expense) benefit	(184)	(1,558)	2,071	2,828
Net Loss	\$ (71,904)	\$ (78,559)	\$ (390,978)	\$ (372,177)
Net Loss Per Share of Common Stock, Basic and Diluted	\$ (0.18)	\$ (0.26)	\$ (1.09)	\$ (1.28)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	406,966	304,890	357,345	289,877
*Non-cash stock-based compensation included in cost of sales and operating expenses:				
Cost of sales	\$ 1,309	\$ 3,192	\$ 7,286	\$ 8,554
Research and development	5,672	13,445	26,959	49,270
Selling, general and administrative	4,836	14,336	27,330	51,799
Total stock-based compensation included in costs and expenses	\$ 11,817	\$ 30,973	\$ 61,575	\$ 109,623

** Excludes depreciation and amortization

CONTACTS

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Media

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IOVANCE

BIO THERAPEUTICS

Corporate Overview

February 2026

ADVANCING IMMUNO-ONCOLOGY

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Forward-Looking Statements

Certain matters discussed in this presentation are “forward-looking statements” of Lovance Biotherapeutics, Inc. (hereinafter referred to as the “Company,” 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 “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “forecast,” “guidance,” “outlook,” “may,” “can,” “could,” “might,” 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, many of which are outside of our control, that may cause actual results, levels of activity, performance, achievements, and outcomes to differ materially from those expressed in or implied by these forward-looking statements. Important factors that could cause actual results, developments, and outcomes 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 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, if approved, and their potential pricing and/or reimbursement by payors, and whether such acceptance is sufficient to support continued commercial development of our products or product candidates; the risk regarding our ability to manufacture our therapies at our iCTC facility, including the risk that our manufacturing capacity at our 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 develop, submit, obtain, or maintain regulatory authority approval of our product candidates; whether clinical trial results from our pivotal studies and other regulatory authorities may support registrational studies and subsequent approvals by regulatory authorities, including the risk that the planned registrational studies for sarcomas may not support approval; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts 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 communications with regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities; the risk that the 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 a marketing application; that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; the risk that we may not recognize revenue for our products; the risk that Proleukin revenues, and other factors such as the number of ATCs, may not serve as a leading indicator for our anticipated operating and financial performance, including our financial guidance and projections; the effects of global and domestic public health events; and other factors, including general economic conditions and regulatory developments, not within our control. Any financial guidance presented in this presentation assumes the following: no material change in our ability to manufacture our products; no material change in payor coverage; no material change in our recognition policies; no new business development transactions not completed as of the period covered by this presentation; and no material fluctuation in

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

2

Approved Products

AMTAGVI
(lifileucel)

U.S. & Canada

PROLEUKIN
(aldesleukin)

Multiple Markets Globally

>1,500

Patients treated with commercial
clinical lovance TIL products

Commercial Launch

~95%

Addressable Patients
within 200 miles of an ATC

>85

Treatment Centers
as of 12/31/25*

~30%

Q4 2025 Quarterly
Revenue Growth

Financials

Full Year 2025 Revenue

\$264M

(Guidance of \$250M-\$300M)

~\$303M

Cash as of 12/31/25

50%

Gross Margin (Q4 2025)

*Includes centers in final stages of readiness or soon to be authorized.
Abbreviations: FDA, U.S. Food and Drug Administration

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The Pioneer in One-Time Cell Therapy for Solid Tumors

Platform technology and robust pipeline in blockbuster solid tumor indications

AMTAGVI¹
(lifileucel)

PROLEUKIN²
(tocilizumab)

\$1B+
U.S. Sales Potential in
2L+ Advanced Melanoma

**~7X U.S. Melanoma
Opportunity
in 2L mNSCLC***

IOVANCE
**Operational Excellence
Focused on Patients**

- First and only approved treatment in 2L+ advanced melanoma
- **~30% quarterly growth** in 4Q25
- ~\$264M total revenue in first calendar year of launch
- **5-year durability:** 34% ORR; ~20% OS; mDOR of >36 months¹
- **Real-world ~44% ORR;** 52% ORR in patients with ≤ 2 prior lines of therapy²

- **High unmet need** with limited treatment options
- SOC: ~13% ORR; ~8 months mDOR; ~13 months mOS
- **Potential best-in-class lifileucel clinical profile:** ~26% ORR; mDOR not reached at 25+ months follow up³
- FTD for NSCLC from U.S. FDA
- Potential launch in 2H27
- **Leverages melanoma** commercial footprint and manufacturing

- **\$303M cash⁴ runway**
- **50% gross margin (40% OpEx)**
- **Ongoing initiatives in cost of sales and gross margin**
- Leading IO pipeline in oncology
- Internal manufacturing
- 5K+ annual capacity for America, Europe & APAC
- 1.5K+ commercial and clinical patients treated

1. Medina et al, ASCO 2025. Pooled Analysis (n=153), Heavily Pre-Treated Patient Population; 2. Karapetyan et al, Tandem Meeting 2026. Physician-assessed confirmed ORR by RECIST v1.1. All evaluable patients received commercial Amtagvi according to the U.S. prescribing information; 3. Interim data cut as of October 10, 2025 of patients with non-squamous NSCLC with minimum cell dose based on FDA feedback for melanoma. 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 December 31, 2025

*Non-squamous mNSCLC without EGFR, ROS1 or ALK genomic mutations

Abbreviations: 2L, second line; FTD, fast track designation; mDOR, median duration of response; mNSCLC, metastatic non-small cell lung cancer; OpEx, operating expenses; ORR, objective response rate; mOS, median overall survival; SOC, standard of care

Strong Platform Supports Backbone IO Therapy for Solid T

lovance Retains Global Portfolio and Technology Platform Rights

AMTAGVI
(lifileucel)

Approved

- U.S.
- Canada

Under Review

- UK 1H26
- Australia 1H26
- Switzerland 1H27
- EU: Updated Submission Planned

PROLEUKIN
(lifelium) (combination 1:2)

Amtagvi Treatment Regimen

- U.S.
- Canada

Additional Clinical Com

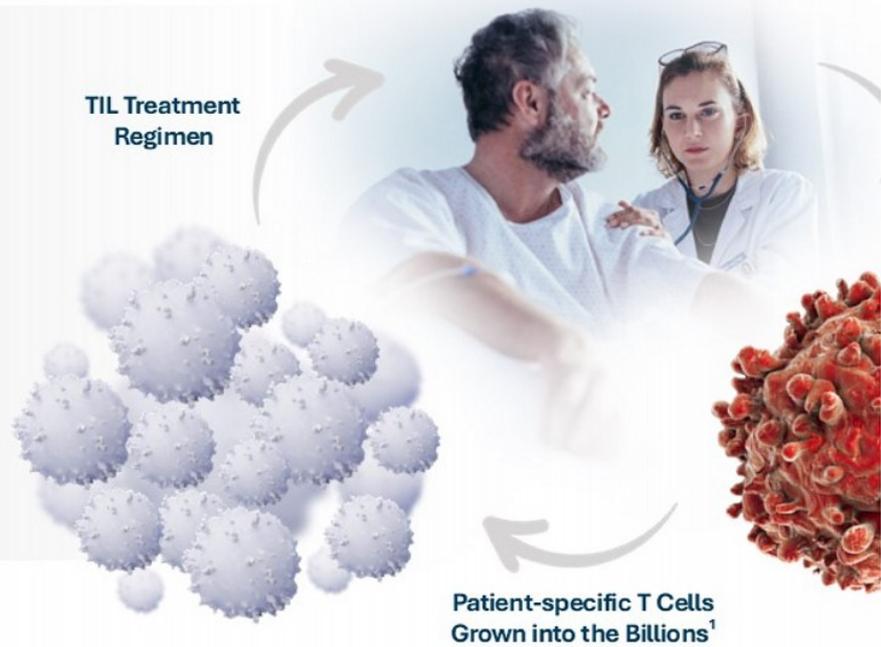
		INDICATION & TREATMENT SETTING	PHASE 1	PHASE 2
Registration-Directed	Lifileucel + pembrolizumab	Frontline advanced melanoma		TILVANCE-301 (FTD, Confirmatory)
	Lifileucel	Post-chemo & anti-PD-1 advanced NSCLC		IOV-LUN-202 (FTD)
	Lifileucel	Post-chemo advanced soft tissue sarcomas (DDLPS or UPS)		IOV-SAR-201*
Lifileucel Pipeline	Lifileucel	Post anti-PD-1 advanced melanoma		IOV-MEL-202
	Lifileucel	Post-chemo & anti-PD-1 endometrial cancer		IOV-END-201
Next-Generation Products	PD-1 Inactivated TIL (IOV-4001)	Post anti-PD-1 advanced melanoma or NSCLC		IOV-GM1-201
	IL-2 analog (IOV-3001)	TIL treatment regimen		IOV-IL2-101
	IL-12 tethered TIL (IOV-5001)	Basket trial		IOV-GE1-201*

*Planned to commence in 2026
Abbreviations: 2L, second line; 4L, fourth line; DDLPS, dedifferentiated liposarcoma; FTD, Fast Track Designation; IO, immuno-oncology; IL-2, interleukin 2; IL-12, interleukin 12; NSCLC, non-small cell lung cancer; PD-1, programmed cell death protein-1; UPS, undifferentiated pleomorphic sarcoma

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 US PI

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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
Soft Tissue Sarcomas	5K	50K
Endometrial	13K	97K

2 Additional markets:



1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program, 2025 Estimates. <https://seer.cancer.gov> (accessed February 2026)
2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022; Zhou et al. BMC Public Health 2025

AMTAGVI[™]
(lifileuce) 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 Therapy:⁷

~5 months

BRAF wild-type
(prior ICI therapy)

~
(prior

1. Chesney J, et al. J Immunother Cancer. 2022; 2. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2025 Estimates. <https://seer.cancer.gov> (accessed August 2025); World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022; 3. Data on file as of July 2025. Includes more than 20,000 patients initial target markets plus additional potential markets; 4. Larkin J, Chiarion-Sileni V, Gonzalez R, et al. NEJM. 5. Ribben C, et al. Lancet. 6. Tawbi HA, Schadendorf D, Lipson EJ, et al. NEJM. 7. Pattnayak JR et al. Cancer. 2020

Abbreviation: 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

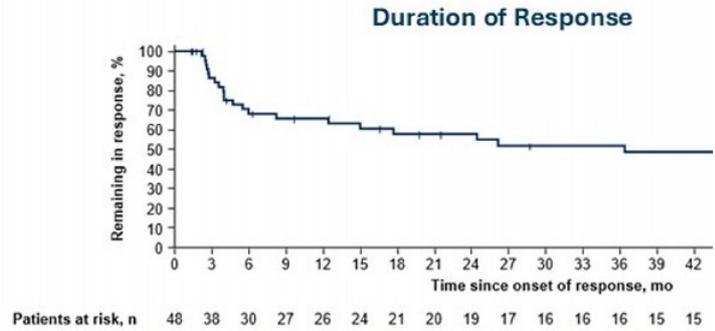
Deep and Durable Responses at 5-Year Follow Up¹

One Third of Responses Remain Ongoing without Subsequent Treatment

ORR
31.4%

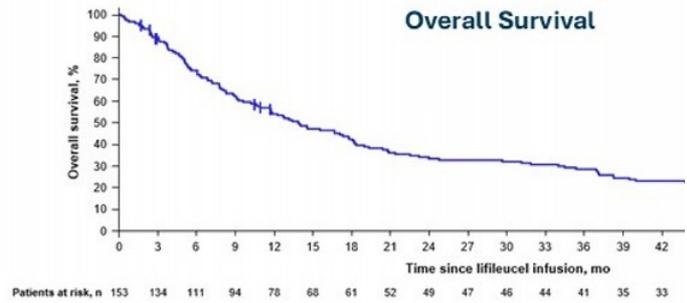
mDOR
36.5 Months

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, media overall survival; NR, not reached; ORR, objective response rate

Best-in-class real-world data driving increased Amtagvi adoption¹

Unprecedented Real-World Response Rates Presented at 2026 Tandem Meetings

44% ORR

(18/41)

73% DCR

(30/41)

Higher Response Rates with Earlier Treatment

52% ORR (12/23)

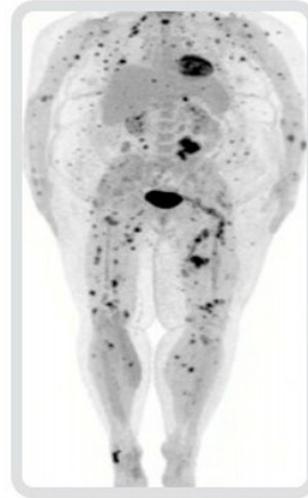
≤ 2 prior lines of therapy

33% ORR (6/18)

≥ 3 prior lines of therapy

Durable Ongoing Partial Response (F
Significant tumor burden reduction at W

Before Lifileucel



Post-Lifileucel

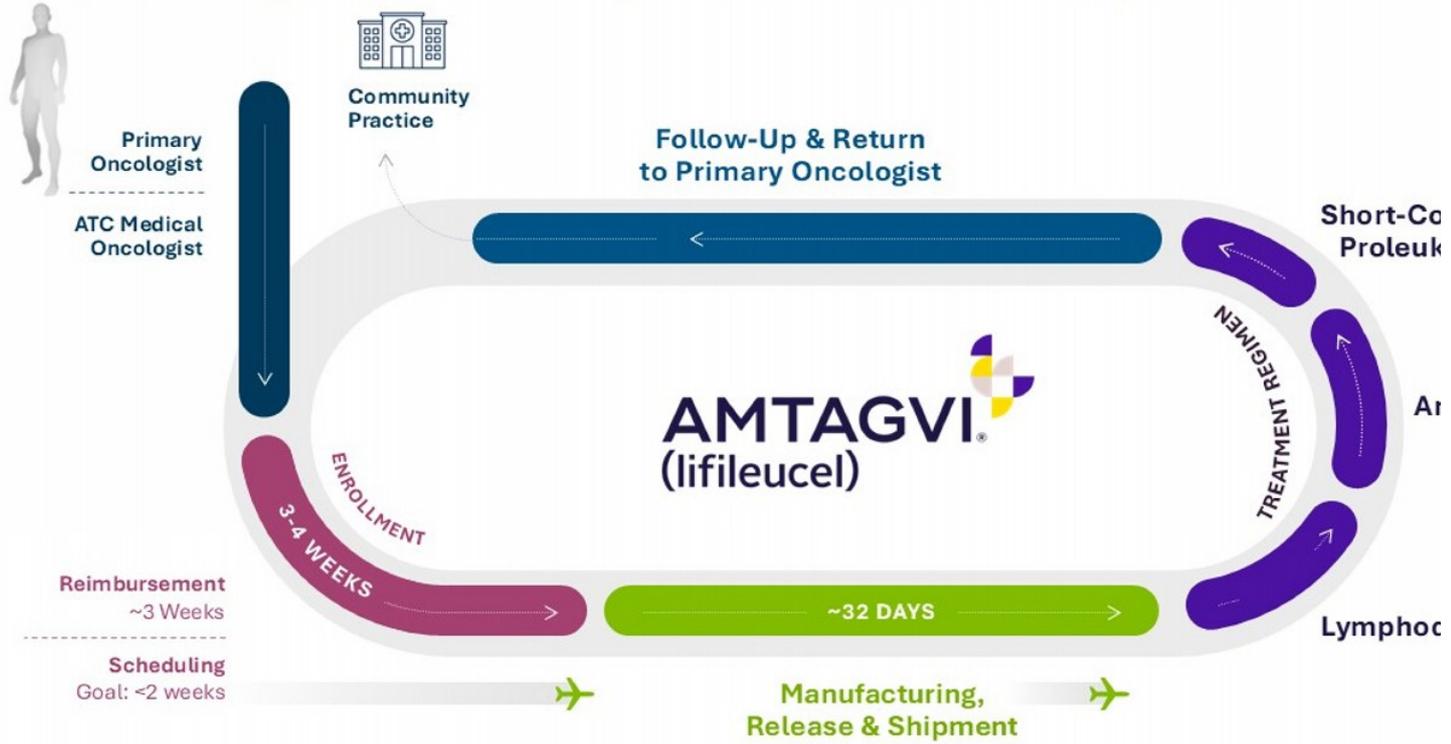


1. Karapetyan L et al. Tandem Meetings 2026.

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: DCR, disease control rate; ORR, objective response rate

Amtagvi® Patient Journey

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



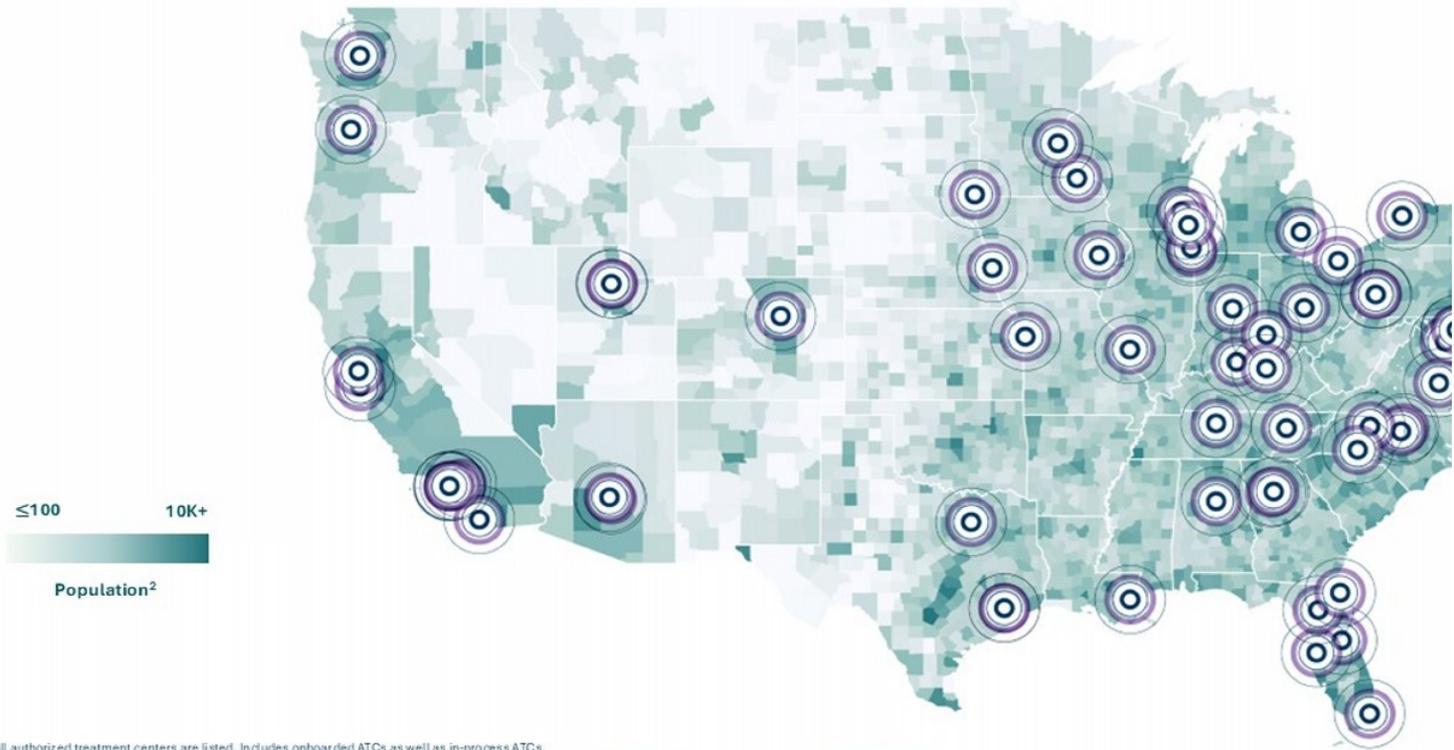
Manufacturing Facility Dedicated to Commercial and Clinical TIL Cell Thera

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



COS = cost of sales

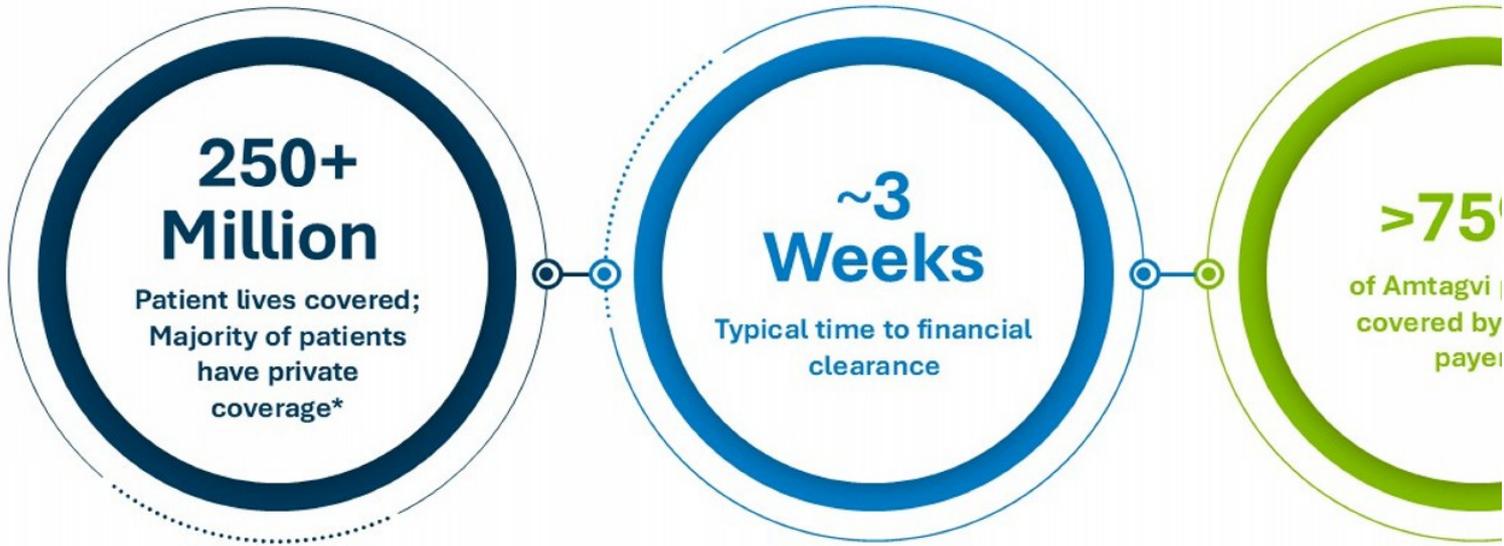
Amtagvi® Authorized Treatment Centers (ATC)



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.

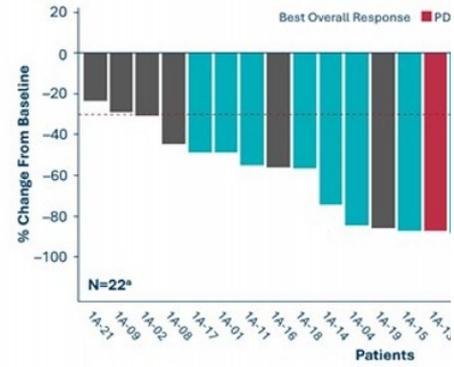
*Unconfirmed CRs, confirmed following data cut.

[†]One patient without a postdose tumor response assessment was not included.

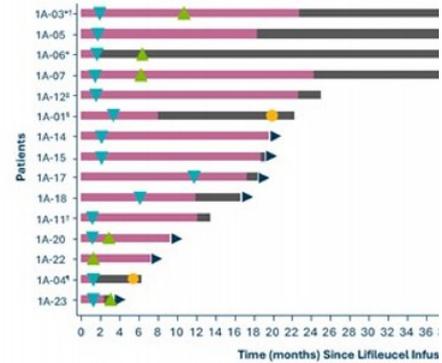
[‡]Target lesion lymph node at baseline decreased by 50% is no longer pathological, and thus is shown here as -100% representing uCR.

Abbreviations: 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 diameters; AE, adverse event; IL-2, interleukin-2; NMA-LD, nonmyeloablative lymphodepletion

Best Percentage Change from Baseline in T

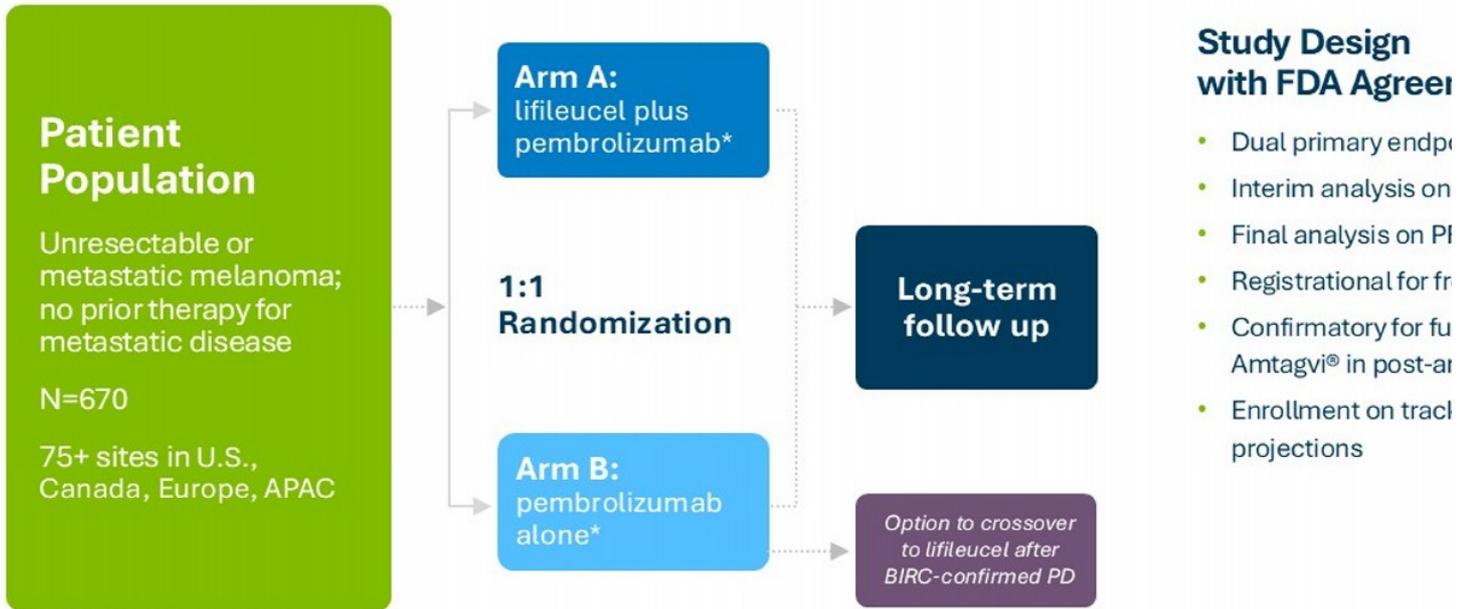


Time to Response and Time of Efficacy Confirmed Responders (PR)



TILVANCE-301 Global Phase 3 and Confirmatory Trial

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



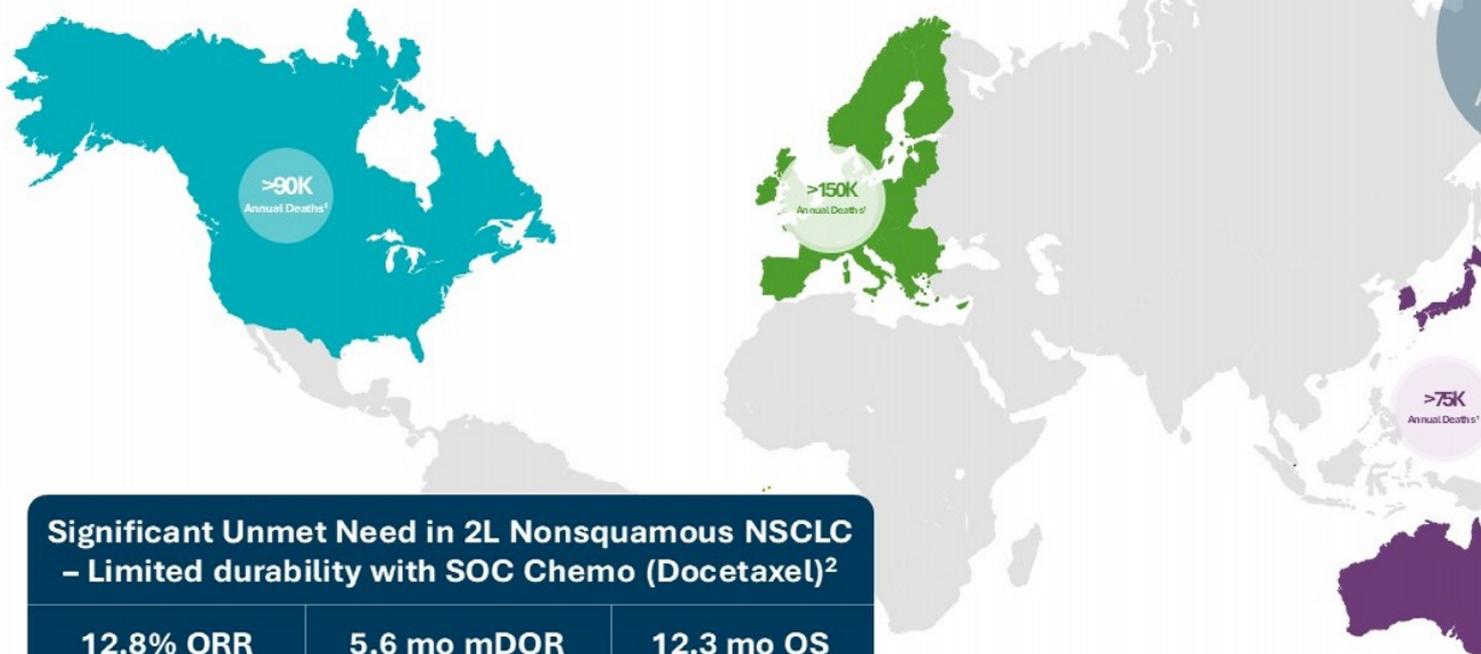
*Pembrolizumab in both arms is started at the same time after randomization.
Abbreviations: BIRC, blinded independent review committee; ORR, objective response rate; PD, progressive disease; PD-1, programmed cell death protein-1; PFS, progression free survival

A microscopic view of cells, likely TILs, with several glowing spots in purple and green, set against a dark blue background.

TIL Therapy Pipeline

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

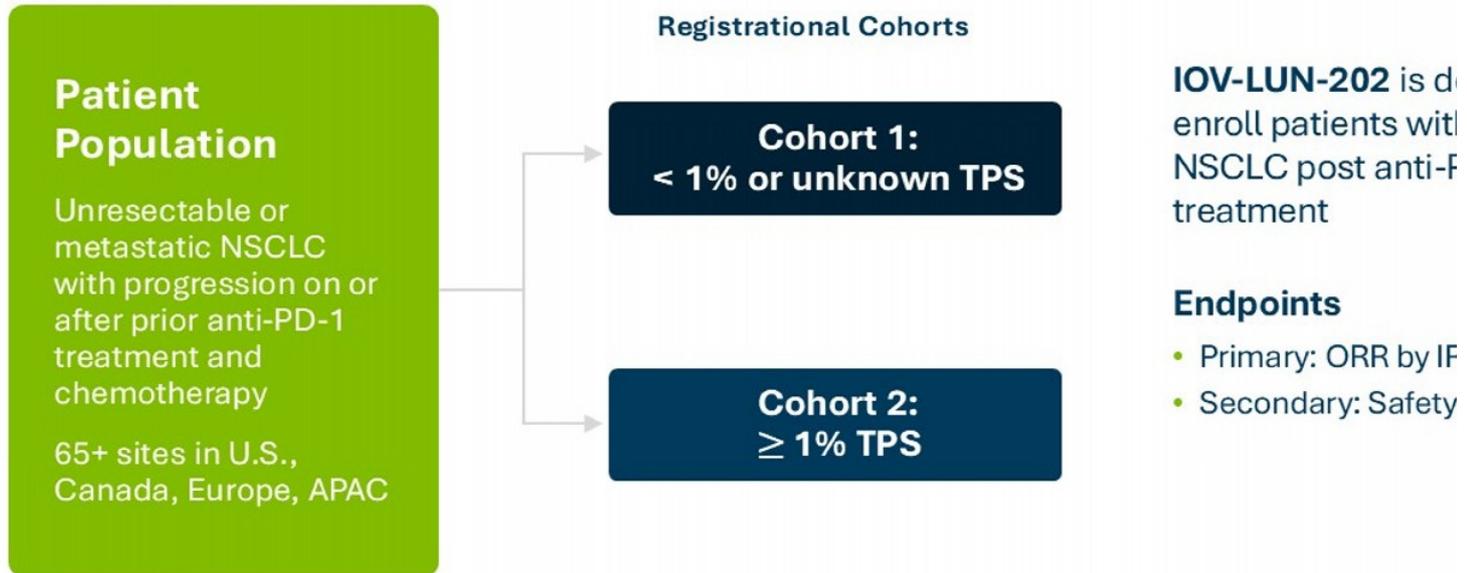
12.3 mo OS

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

Fast Track Designation in Second-Line Nonsquamous mNSCLC

One-Time Therapy with Unprecedented Durability and Potential Best-in-Class Clinical Profile¹

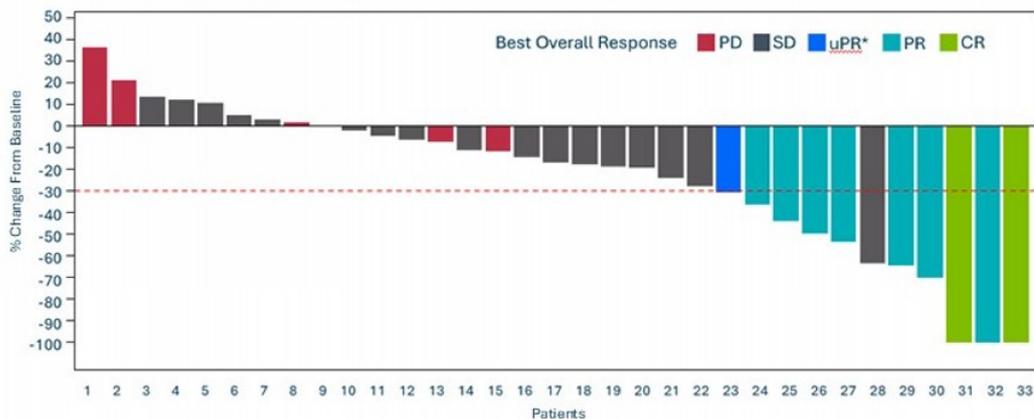
25.6% ORR

(n=39; RECIST 1.1)

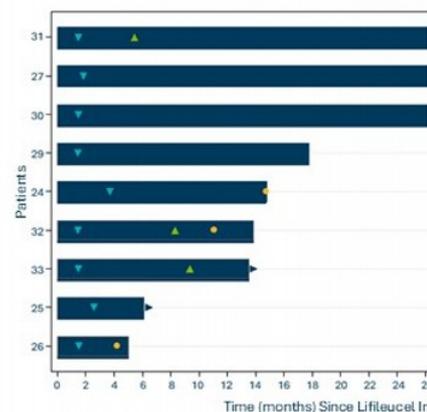
mDOR Not Reached

(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 in melanoma. Patients progressed on or after chemotherapy and anti-PD-1 therapy for mNSCLC with out EGFR, ROS1 or ALK genomic mutations and received at least one line of FDA-approved targeted therapy if indicated by other actionable tumor mutations. ² Time to response, time on assessment for confirmed responders (PR or better). A bar is presented for each patient starting from date of lifileucef 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.

Abbreviations: 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 NSCLC

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

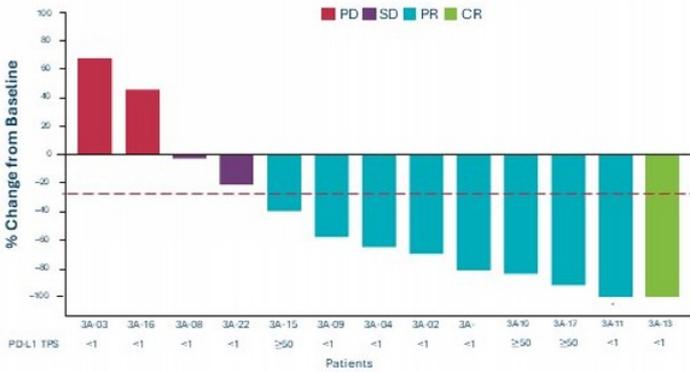
64.3% ORR EGFR^{WT}

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

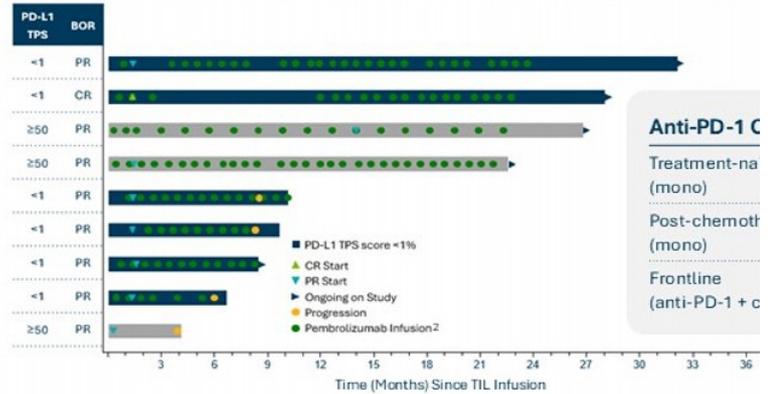
mDOR not reached (median follow-up 26.5 mo)

- Safety consistent with lovance TIL combination study
- 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})



1. Creelan et al, STC 2024
 2. KEYTRUDA USP; OPDIVO USPI
 *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

Significant Market Opportunity for Advanced Tissue Sarcor

Practice-changing potential in rare, high grade, aggressive refractory UPS & DDLPS with very high unmet

>8K

Patients/yr (US & Europe)

>3K

US annual cases¹

>5K

Europe annual cases²

>3.5K

Patients with advanced disease³

50%

ORR via RECIST v1.1

2.33

Mean Prior Lines of Therapy

117 r

Baseline Me

Deep responses improved over time

- All evaluable patients had significant disease burden
- Safety consistent with lifileucel in other indications

Current 2L SOC has low ORR (<5%) with short dural

- No approved ICI options

Phase 2 registrational trial to commence in 2Q 2026

- Targeting expedited pathways for registration
- Plan to explore additional high grade soft tissue sarcoma su

1.. CancerMPact Patient Metrics for US Soft Tissue Sarcoma (accessed February 2026); 2. Zhou et al. BMC Public Health 2025; 3. CancerMPact Treatment Architecture for Sarcoma for the US & EU5 (May 2025) to inform treatment rates in the US and EU5. 4. Parikh RC, et al. Cancer. 2018. 5. Italiano A, et al. Ann Oncol. 2012;6. Jones RL et al. Ann Oncol. 2023. Abbreviations: 2L, second line; DDLPS, dedifferentiated liposarcoma; DCR, disease control rate; ICI, immune checkpoint inhibitor; ORR, objective response rate; RECIST, Response Evaluation Criteria in Solid Tumors; SOD, sum of diameter (in millimeter); UPS, undifferentiated pleomorphic sarcoma

Potential Market for Advanced Endometrial Cancer

Immunosensitive Tumor Type with Significant Unmet Need in 2L+

>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. 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 (NCT0648

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 investigator
- **Secondary:** CR rate, DOR, OS, safety and tolerability
- Subgroup analyses specific
- Potential to expand / continue registrational trial
- First patient enrolled Q4 2024

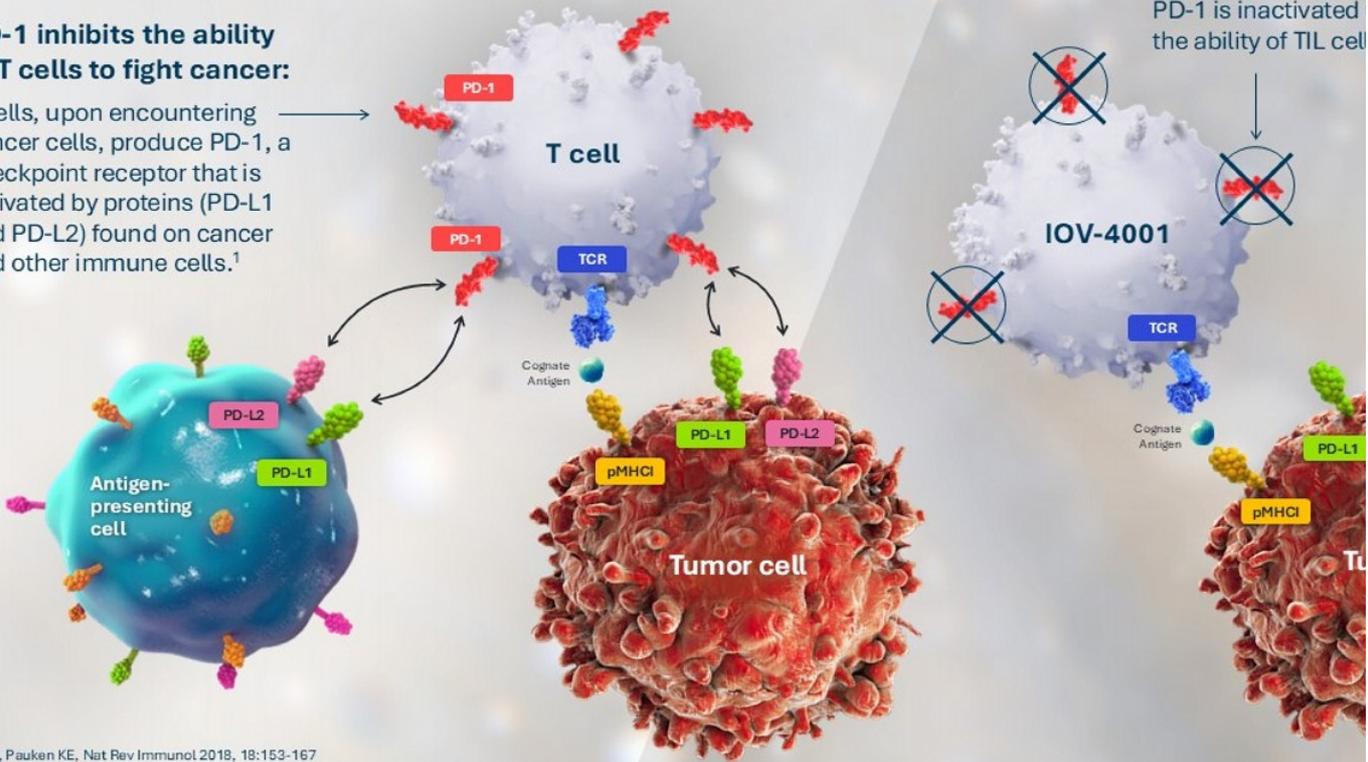
*Sample size and study population of registrational ph2 study will be determined after PoC final analysis

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



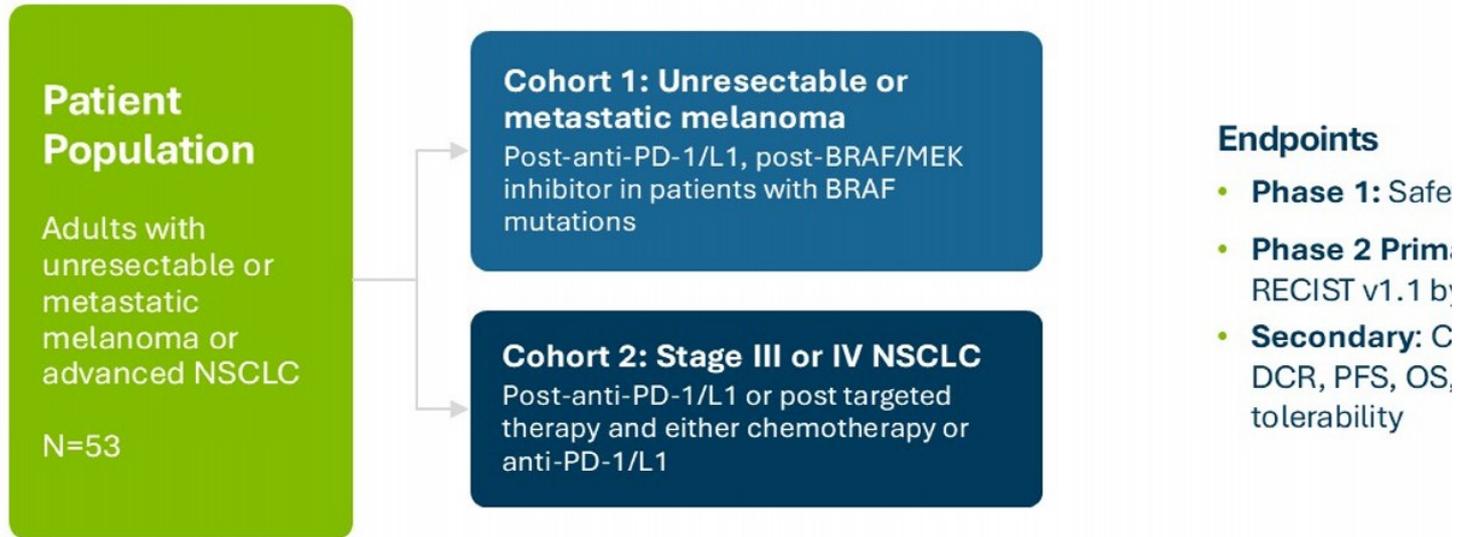
2 PD-1 Inactivated Avoid Checkpoint

PD-1 is inactivated the ability of TIL cell

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

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

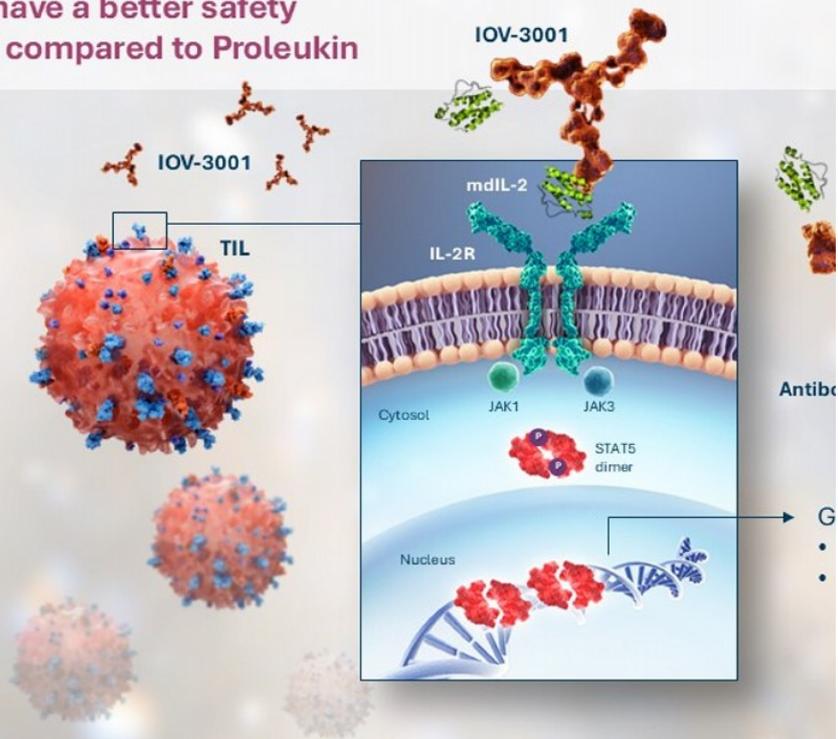
IOV-3001: Next Generation IL-2 for TIL Supportive Regimen

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 immunosuppressive 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



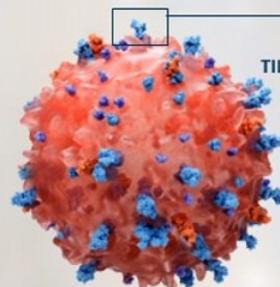
NK and NK-T cell activation and proliferation³



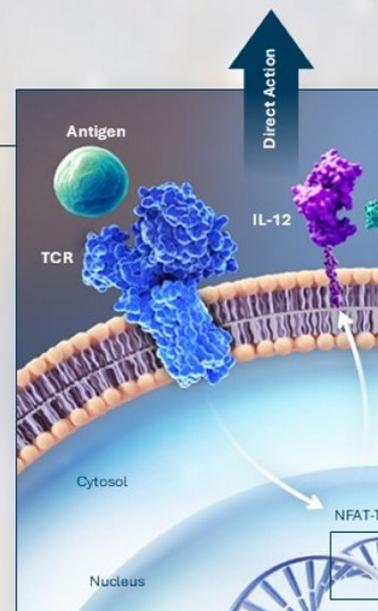
CD8⁺ T cell activation and proliferation⁴



CD4⁺ T cell differentiation to Th1⁵



TIL



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.

Abbreviations: 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

2025 Revenue (First Full Year of Launch)

~\$264M

FY25 Guidance of \$250M-\$300M Achieved

Cash position (12/31/25)

\$303M

Cash runway into

Q3 2027¹

Revenue Growth • Margin Improvement • Cost Control

1. Includes anticipated revenue from Amtagvi® and Proleukin® and anticipated savings from strategic restructuring announced on August 7, 2025

2. Preferred shares are shown on an as-converted basis.



IOVANCE
BIOTHERAPEUTICS

Thank You

ADVANCING IMMUNO-ONCOLOGY

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