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 16, 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, CA**	**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 2.02. Results of Operations and Financial Condition.

Iovance Biotherapeutics, Inc. (the "Company") reports that as of December 31, 2023, the Company had approximately $346.3 million in cash, cash equivalents, investments, and restricted cash ($114.9 million of cash and cash equivalents, $165.0 million in short-term investments, and $66.4 million in restricted cash).

The foregoing information reflects the Company's preliminary estimates with respect to cash, cash equivalents, investments, and restricted cash. This announcement is not a comprehensive statement of the Company's financial results and is subject to completion of an audit by the Company's independent registered public accounting firm. The Company's final financial results will be issued upon completion of such audit and may vary from these preliminary estimates.

Item 8.01. Other Events.

On February 16, 2024, the Company issued a press release announcing that AMTAGVI® (lifileucel) has received U.S. Food and Drug Administration accelerated approval for the treatment of advanced melanoma. The Company also updated its corporate presentation that it uses for presentations at healthcare conferences and to analysts, current stockholders, and others.

A copy of the press release and the Company's corporate presentation are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated by reference herein.

The information contained in Item 2.02 of this Current Report on Form 8-K is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated February 16, 2024
99.2	Iovance Biotherapeutics, Inc., Corporate Presentation - February 16, 2024
104	Cover Page Interactive Data File, formatted in Inline XBRL and included as Exhibit 101

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Iovance Biotherapeutics, Inc.

Dated: February 20, 2024

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

Iovance's AMTAGVI™ (lifileucel) Receives U.S. FDA Accelerated Approval for Advanced Melanoma

AMTAGVI is the first FDA-approved T cell therapy for a solid tumor cancer and first treatment option for advanced melanoma after anti-PD-1 and targeted therapy

AMTAGVI deploys patient-specific immune cells that recognize and fight cancer

SAN CARLOS, Calif., February 16, 2024 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company focused on innovating, developing and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) cell therapies for patients with cancer, today announced that the U.S. Food and Drug Administration (FDA) has approved AMTAGVI™ (lifileucel) suspension for intravenous infusion. AMTAGVI is a tumor-derived autologous T cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. This indication is approved under an accelerated approval based on overall response rate (ORR) and duration of response. Iovance is also conducting TILVANCE-301, a Phase 3 trial to confirm clinical benefit.

AMTAGVI is the first and the only one-time, individualized T cell therapy to receive FDA approval for a solid tumor cancer. The proposed mechanism for AMTAGVI offers a new cell therapy approach that deploys patient-specific T cells called TIL cells. When cancer is detected, the immune system creates TIL cells to locate, attack, and destroy cancer. TIL cells recognize distinctive tumor markers on the cell surface of each person's cancer. When cancer develops and prevails, the body's natural TIL cells can no longer perform their intended function to fight cancer.

AMTAGVI is manufactured using a proprietary process to collect and expand a patient's unique T cells from a portion of their tumor. AMTAGVI returns billions of the patient's T cells back to the body to fight their cancer.***** Authorized Treatment Centers (ATCs) will administer AMTAGVI to patients as part of a treatment regimen that includes lymphodepletion and a short course of high-dose PROLEUKIN® (aldesleukin).

"The accelerated approval of AMTAGVI™ is the first step in realizing Iovance's ambition to usher in the next generation of cell therapy by bringing this breakthrough to patients with advanced solid tumors," said Frederick Vogt, Ph.D., J.D., Interim Chief Executive Officer and President of Iovance. "Given the significant unmet needs in the advanced melanoma community, we are proud to offer a personalized, one-time therapeutic option for these patients. We are continuing our development efforts to address additional unmet medical needs in patients with solid tumor cancers, making our novel cell therapies available to more patients with melanoma and other types of cancers."

Each year, approximately 8,000 people in the U.S. die from melanoma.[1] Until now, there have been no FDA-approved treatment options for patients with advanced melanoma whose disease progressed following initial treatment with an immune checkpoint inhibitor and, if appropriate, targeted therapy.

“The approval of AMTAGVI™ offers hope to those with advanced melanoma, who have progressed following initial standard of care therapies, as the current treatment options are not effective for many patients,” said Samantha R. Guild, J.D., President, AIM at Melanoma Foundation. “This one-time cell therapy represents a promising innovation for the melanoma community, and we are excited by its potential to transform care for patients who are in dire need of additional therapeutic options.”

The FDA approval is based on safety and efficacy results from the C-144-01 clinical trial. C-144-01 is a global, multicenter trial investigating AMTAGVI in patients with advanced melanoma previously treated with anti-PD-1 therapy and targeted therapy, where applicable. AMTAGVI demonstrated deep and durable responses. The primary efficacy analysis set included 73 patients from Cohort 4 who received the recommended AMTAGVI dose from an approved manufacturing facility. Among the 73 patients, 31.5% achieved an objective response by Response Evaluation Criteria in Solid Tumors (RECIST 1.1) with a median duration of response not reached at 18.6 months follow up,[2] (43.5% of responses had a duration greater than 12 months). Additionally, the supporting pooled efficacy set included a total of 153 patients from Cohort 4 and Cohort 2. Among these 153 patients, 31.4% achieved an objective response by RECIST 1.1 with a median duration of response not reached at 21.5 months follow up,[2] (54.2% of responses had a duration greater than 12 months). The detailed results of clinical trial C-144-01 are published in The Journal for ImmunoTherapy of Cancer (Chesney 2022).

AMTAGVI is for autologous use only. AMTAGVI has a boxed warning for treatment-related mortality, prolonged severe cytopenia, severe infection, and cardiopulmonary and renal impairment. Warnings and precautions include treatment-related mortality, prolonged severe cytopenia, internal organ hemorrhage, severe infection, cardiac disorder, respiratory failure, acute renal failure, and hypersensitivity reactions. Please see Important Safety Information and Prescribing Information below.

“This landmark FDA approval reflects significant advancements in TIL cell therapy since we initially showed that TIL cells isolated from patients with metastatic melanoma could be expanded in the lab and returned to the patient to mediate cancer regression,” said Steven Rosenberg, M.D., Ph.D., Chief, Surgery Branch, National Cancer Institute, and a TIL and immunotherapy pioneer. “This approval is transformative for the entire research field and supports continued investigation of TIL cell therapy across additional types of solid tumors.”

“One-time treatment with AMTAGVI™ offered clinically meaningful and deep, durable responses in the Phase 2 clinical trial, and I am excited by its potential as a much-needed new treatment option for the many advanced melanoma patients who progress on the current standard of care,” said Dr. Alexander N. Shoushtari, Melanoma Oncologist & Cellular Therapist at Memorial Sloan Kettering Cancer Center. “This welcome news represents an important step forward in harnessing cell therapy to treat solid tumors,” added Dr. Jae Park, Chief of Cellular Therapy Service at Memorial Sloan Kettering Cancer Center.

AMTAGVI will be manufactured in Philadelphia at the Iovance Cell Therapy Center (iCTC), with capacity for up to several thousand patients annually, including a nearby contract manufacturer. Additional expansion at iCTC is underway which will significantly increase this capacity over the next few years. iCTC is the first FDA-approved, centralized, and scalable manufacturing facility dedicated to producing TIL cell therapies for patients with solid tumors. AMTAGVI must be administered in an ATC, and more than 30 ATCs are prepared to collect and ship tumor tissue from patients for AMTAGVI manufacturing.

Iovance is dedicated to providing access to AMTAGVI for patients with advanced melanoma. A comprehensive support program, IovanceCares™, is now available for patients and ATCs throughout the treatment journey. IovanceCares will also offer copay support, financial assistance, and travel and lodging assistance for eligible patients during AMTAGVI therapy. For more information, physicians and patients may call 833-400-IOVA (4682) or visit www.iovancecares.com.

Iovance is investigating AMTAGVI in frontline advanced melanoma in the Phase 3 confirmatory trial, TILVANCE-301, as well as additional solid tumor types, which represent 91% of the cancers in the U.S.[1] For more information, please visit: https://www.iovance.com/clinical-trials/.

[1]National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. https://seer.cancer.gov accessed February 2024.

[2]Kaplan-Meier estimate of median potential follow-up for duration of response.

*A single dose of AMTAGVI contains 7.5×10^9 to 72×10^9 viable cells.

Webcast and Conference Call

Iovance will host a conference call and live audio webcast to discuss the FDA approval of AMTAGVI today, details will be shared in a subsequent announcement.

About the C-144-01 Clinical Trial

C-144-01 is a global, multicenter Phase 2 study in which patients received treatment with lifileucel. The study enrolled patients with metastatic melanoma who were previously treated with at least one systemic therapy, including a PD-1 blocking antibody, and if BRAF V600 mutation-positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor. Efficacy was established on the basis of objective response rate (ORR), and duration of response (DOR) by Independent Review Committee (IRC) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. The pivotal Cohort 4 and supportive Cohort 2 of Study C-144-01 enrolled patients that met the same primary eligibility criteria, had the same assessments, and had received the same regimen and AMTAGVI that was produced using the same manufacturing process, and product formulation. The detailed results of C-144-01 were published in the Journal for ImmunoTherapy of Cancer in 2022.

What is AMTAGVI (lifileucel)?

AMTAGVI is a prescription medicine used to treat adults with a type of skin cancer that cannot be removed surgically or has spread to other parts of the body called unresectable or metastatic melanoma.

AMTAGVI is used when your melanoma has not responded or stopped responding to a PD-1 blocking drug either by itself or in a combination, and if your cancer is BRAF mutation positive, a BRAF inhibitor drug with or without a MEK inhibitor drug that has also stopped working.

The approval of AMTAGVI is based on a study that measured response rate. Continued approval for this use may depend on the results of an ongoing study to confirm benefit.

Important Safety Information

What is the most important information that I should know about AMTAGVI?

You will likely be in a hospital prior to and after receiving AMTAGVI.

Before taking AMTAGVI, tell your healthcare provider about all of your medical conditions, including if you:

- Have any lung, heart, liver or kidney problems
- Have low blood pressure
- Have a recent or active infection or other inflammatory conditions including cytomegalovirus (CMV) infection, hepatitis B or C or human immunodeficiency virus (HIV) infection
- Are pregnant, think you may be pregnant, or plan to become pregnant
- Are breastfeeding
- Notice the symptoms of your cancer are getting worse
- Have had a vaccination in the past 28 days or plan to have one in the next few months
- Have been taking a blood thinner

Tell your doctor about all the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive AMTAGVI?

- AMTAGVI is made from your surgically removed tumor. Tumor derived T cells are grown in a manufacturing center at the end of which they number in the billions of cells.
- Your tumor tissue is sent to a manufacturing center to make AMTAGVI. It takes about 34 days from the time your tumor tissue is received at the manufacturing center until AMTAGVI is available to be shipped back to your healthcare provider, but the time may vary. Your AMTAGVI will be provided in 1-4 patient-specific infusion bag(s) containing 100 mL to 125 mL of viable (alive) cells per bag.
- After your AMTAGVI arrives at your treating institution, your healthcare provider will give you lymphodepleting chemotherapy to prepare your body.
- Approximately 30 to 60 minutes before you are given AMTAGVI, you may be given other medicines including:
    - Medicines for an allergic reaction (anti-histamines)
    - Medicines for fever (such as acetaminophen)
- Your AMTAGVI will be provided in 1 to 4 infusion bag(s) containing 100 mL to 125 mL of viable cells per bag. When your body is ready for AMTAGVI infusion, your healthcare provider will give AMTAGVI to you by intravenous infusion. This usually takes less than 90 minutes.

After getting AMTAGVI

Beginning 3 to 24 hours after AMTAGVI is given, you may be given up to 6 doses of IL-2 (aldesleukin) every 8 to 12 hours via intravenous infusion. Your doctor may discontinue IL-2 (aldesleukin) infusion any time if you have severe side effects.

You will have to stay in the hospital until you have completed the IL-2 (aldesleukin) treatment and you have recovered from any serious side effects associated with the AMTAGVI treatment.

You should plan to stay within 2 hours of the location where you received your treatment for several weeks after getting AMTAGVI. Your healthcare provider will check to see if your treatment is working and help you with any side effects that occur.

What are the possible side effects of AMTAGVI?

The most common side effects of the AMTAGVI treatment include chills, fever, low white blood cell count (may increase risk of infections), fatigue, low red blood cell count (may cause you to feel tired or weak), fast or irregular heartbeat, rash, low blood pressure, and diarrhea.

These are not all the possible side effects of the AMTAGVI treatment. Talk with your healthcare provider for more information about AMTAGVI. You can ask your healthcare provider for information about AMTAGVI that is written for healthcare professionals.

You may report side effects to Iovance at 1-833-400-4682, or to the FDA, at 1-800-FDA-1088 or at www.fda.gov/medwatch.

Please see Full Prescribing Information and Patient Information, including Boxed Warning, for additional Important Safety Information.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) cell 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, which may be a promising option for patients with cancer. For more information, please visit 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”). All such written or oral statements, including, without limitation, the statements by Frederick Vogt, Ph.D., J.D., Samantha R. Guild, J.D., Steven Rosenberg, M.D., Ph.D., Dr. Alexander N. Shoushtari, and Dr. Jae Park, made in this press release, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by 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,” “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, including AMTAGVI, for which we obtain U.S. Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”), or other regulatory authority approval; the risk that the EMA or other regulatory authorities may not approve or may delay approval for our biologics license application (“BLA”) submission for lifileucel in metastatic melanoma; the acceptance by the market of our products, including AMTAGVI, and their 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 acceptance is sufficient to support continued commercialization or development of our products, including AMTAGVI, or product candidates, respectively; our ability or inability to manufacture our therapies using third party manufacturers or at our own facility may adversely affect our commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk regarding the successful integration of the recent Proleukin acquisition; the risk that the successful development or commercialization of our products, including AMTAGVI, may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; the risk that future competitive or other market factors may adversely affect the commercial potential for AMTAGVI; the risks 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, our product candidates; 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 subsequent approvals by the 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 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 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 changing landscape of care for 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 clinical trials based on 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 regulatory authorities may 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 lung cancer clinical trials); 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 effects of the COVID-19 pandemic; and other factors, including general economic conditions and regulatory developments, not within our control.

CONTACTS

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Senior Director, Investor Relations & Corporate Communications
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Exhibit 99.2

IOVANCE BIOTHERAPEUTICS

Corporate Overview

February 16, 2024

ADVANCING IMMUNO-ONCOLOGY

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," "
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"potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "forecast," "guidance," "outlook," "may," "could," "might," "will," "should," or o
convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions a
made in light of management's experience and perception of historical trends, current conditions, expected future developments, and other factors believed to be a
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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-
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 re
successfully commercialize our products, including AMTAGVI, for which we obtain U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA")
authority approval; the risk that the EMA or other regulatory authorities may not approve or may delay approval for our biologics license application ("BLA") submiss
metastatic melanoma; the acceptance by the market of our products, including AMTAGVI, and their potential pricing and/or reimbursement by payors, if approved (i
product candidates), in the U.S. and other international markets and whether such acceptance is sufficient to support continued commercialization or developmen
including AMTAGVI, or product candidates, respectively; our ability or inability to manufacture our therapies using third party manufacturers or at our own facility ma
commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk rega
integration of the recent Proleukin acquisition; the risk that the successful development or commercialization of our products, including AMTAGVI, may not generate
from product sales, and we may not become profitable in the near term, or at all; the risk that future competitive or other market factors may adversely affect the co
AMTAGVI; the risks related to the timing of and our ability to successfully develop, submit, obtain, or maintain FDA, EMA, or other regulatory authority approval of, or
respect to, our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authoritie
registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities, including the risk that the planned single arm Phase 2 IOV-LUN-20
support registration; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflecte
of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; the risk that enrollment may need to be adjusted for our trials and coho
based on FDA and other regulatory agency input; the risk that the changing landscape of care for cervical cancer patients may impact our clinical trials in this indicat
may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA, EMA, or other regulatory authorities; t
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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 authoriza
unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; the effects of the COVID-19 pa
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

Platform

700+
Patients Treated with Iovance TIL

2
Manufacturing Sites FDA Approved for Commercial Production

22-day
Proprietary Manufacturing Process

Portfolio

2 Commercial Products
AMTAGVI (lifileucel) PROLEUKIN (aldesleukin)

7 Active Clinical Trials

5 Tumor Types in Clinic

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

People & Assets

~$428M
Cash Position as of 9/30/23

60+
US and International Patents

500+
Employees

Abbreviations: BTD=Breakthrough Therapy Designation; FDA=U.S. Food and Drug Administration; RMAT=Regenerative Medicine Advanced Therapy Designation

Iovance Solid Tumor Portfolio Highlights

AMTAGVI™ (lifileucel) Suspension for IV infusion

Post-anti-PD-1 advanced melanoma
NOW APPROVED

PROLEUKIN® (aldesleukin) Recombinant IL-2

AMTAGVI treatmen
Advanced melanoma, r

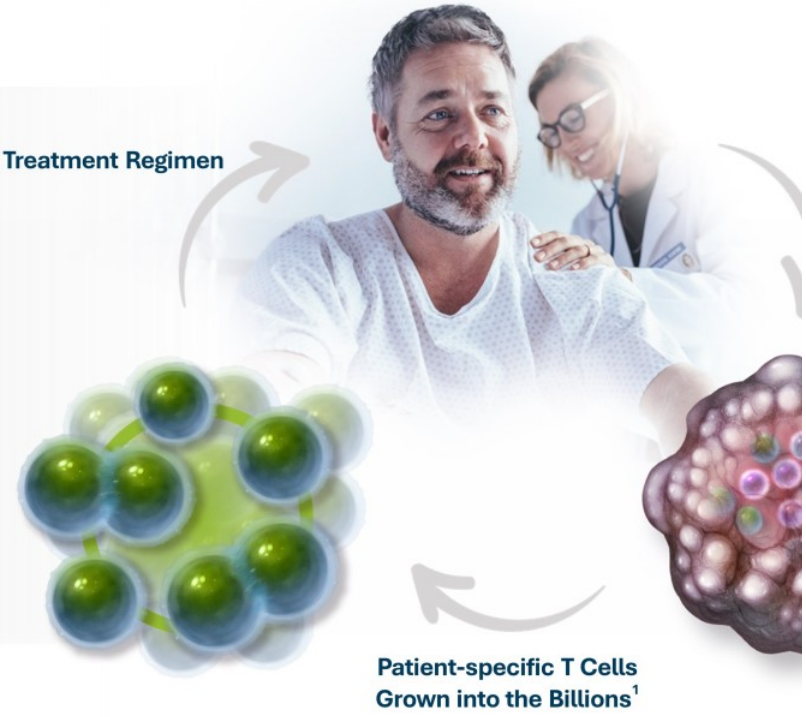
	CANDIDATE	INDICATIONS	PHASE 1	PHASE 2
Registration-Directed	Lifileucel + pembro	Frontline advanced melanoma	TILVANCE-301 Phase 3	
	LN-145	2L post-chemo & post-anti-PD-1 advanced NSCLC	IOV-LUN-202: Cohorts 1&2	
	Lifileucel	Post-chemo & post-anti-PD-1 cervical	C-145-04: Cohort 2	BTD, ODD
Additional Pipeline	LN-145 + pembro	1L chemo and anti-PD-1 naïve cervical	C-145-04: Cohort 3*	
	Lifileucel	2L post-chemo & post-anti-PD-1 endometrial	*Planned Phase 2*	
	LN-145, LN-145 + ICI	2-4L incl. post-anti-PD-1 advanced NSCLC	IOV-COM-202: Cohorts 3A, 3B*,3C	
	LN-145 + ICI	1L advanced melanoma	IOV-COM-202: Cohort 1A	
Next Generation	PD-1 Inactivated TIL (IOV-4001)	Post anti-PD1 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	
	LN-145 Gen 3 + core biopsy	2L post-chemo & post-anti-PD-1 advanced NSCLC	IOV-LUN-202: Cohort 3	

*Enrollment complete
Abbreviations: 1L=first line; 2L=second line; 4L=fourth line; BTD=Breakthrough Therapy Designation; FTD=Fast Track Designation; ipi/nivo=ipilimumab/nivolumab; NSCLC=non-small cell lung cancer; ODD=Orphan Drug Designation; PD-1=programmed cell death protein-1; RMAT=Regenerative Medicines Advanced Therapy; TIL=tumor infiltrating lymphocytes

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

AMTAGVI™ (lifileucel):
First and only one-time, individualized T cell therap
approved by FDA for a solid tumor cancer

Actor portrayal and not a real image of a T cell.

NOW APPROVED

The first and only FDA-approved
therapy for previously treated a
(unresectable or metastatic) me

AMTAGVI™ is a one-time treatment unique for each patient.

Indication

AMTAGVI (lifileucel) is a tumor-derived autologous T cell immunotherapy indicated for the treatmer unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRA a BRAF inhibitor with or without a MEK inhibitor.

This indication is approved under accelerated approval based on objective response rate (ORR). Co indication may be contingent upon verification and description of clinical benefit in a confirmator

Important Safety Information

WARNING: TREATMENT-RELATED MORTALITY, PROLONGED SEVERE CYTOPENIA, SEVERE INFECTION, RENAL IMPAIRMENT

- Monitor patients for prolonged severe cytopenia and monitor for internal organ hemorrhage
- Administer filgrastim or a biosimilar product to patients beginning Day 1 after AMTAGVI and co absolute neutrophil count (ANC) is greater than 1000 per mm^3 for 3 consecutive days, or per in
- Treat severe infections
- Monitor cardiopulmonary and renal functions throughout the treatment course

Administer in an inpatient hospital setting. An intensive care facility and specialists skilled in car care medicine must be available.

1. AMTAGVI USPI

U.S. Unmet Medical Need for Metastatic Melanoma Therap

AMTAGVI is the First FDA Approved Treatment Option After Progression on ICI (Anti-PD-1) Therapy and BRA inhibitors

15k

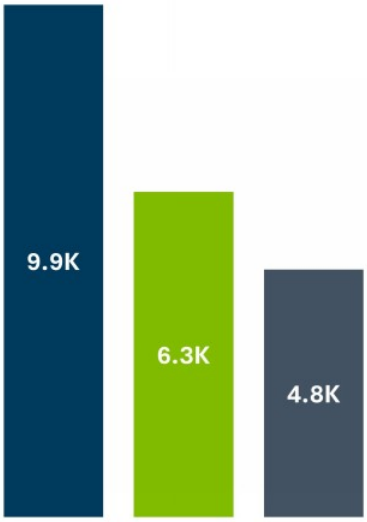
Annual new cases of advanced melanoma in U.S.[1]

8k

Annual deaths in U.S.[2]

Melanoma Drug-Treated Population in 2021

Unresectable / Metastatic (US) [3]



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1. Estimate of US incidence (2021) of unresectable or metastatic melanoma based on secondary and primary market research
2. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. https://seer.cancer.gov accessed February 2024
3. Clarivate DRG Disease Landscape (2021)
4. Larkin et al, NEJM 2019; Robert et al, Lancet Oncology 2019; Tawbi et al, NEJM 2022

Abbreviations: 1L=first line therapy, 2L=second line therapy, 3L=third line therapy, 4L=fourth line therapy; ICI=immune checkpoint inhibitor; PD-1=programmed cell death protein-1

AMTAGVI™ Delivered Deep and Durable Responses

Cohort 4 Pivotal[1] (N=73)

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

mDOR Not Reache
18.6 months follow
(Range: 1.4+,26.3+; 95%

Supportive Pooled Data[1] (n=153)

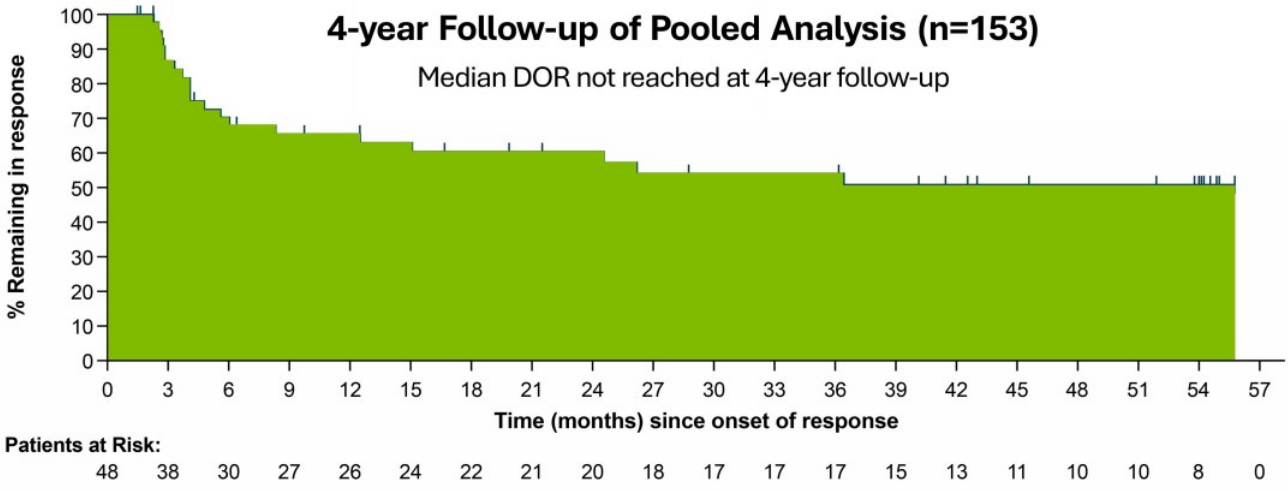
ORR 31.4%
(95%CI:24.1,39.4)

mDOR Not Reached
21.5 months follow
(Range: 1.4+,

1. AMTAGVI USPI
2. Data on file.

CI, confidence interval; mDOR, median duration of response; NR, not reached.

AMTAGVI™ C-144-01 4-year Follow Up



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

ORR

mDOR

48.1

1. Medina et al, ESMO IO 2023.

AMTAGVI™ Patient Journey

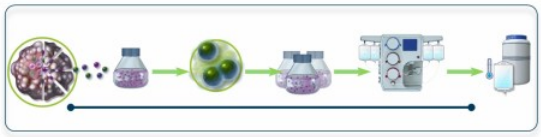
AMTAGVI Autologous T Cell Therapy

Treatment Decision & Reimbursement Approval

Scheduling & Tumor Tissue Procurement

AMTAGVI starts with a piece of the patient's tumor tissue

T Cell Therapy Manufacturing & Release Testing



TIL cells are grown into the billions in a manufacturing facility

Treatment Reg & Monitori

- Lymphodepl
- **AMTAGVI™ (**
- Short-Cours

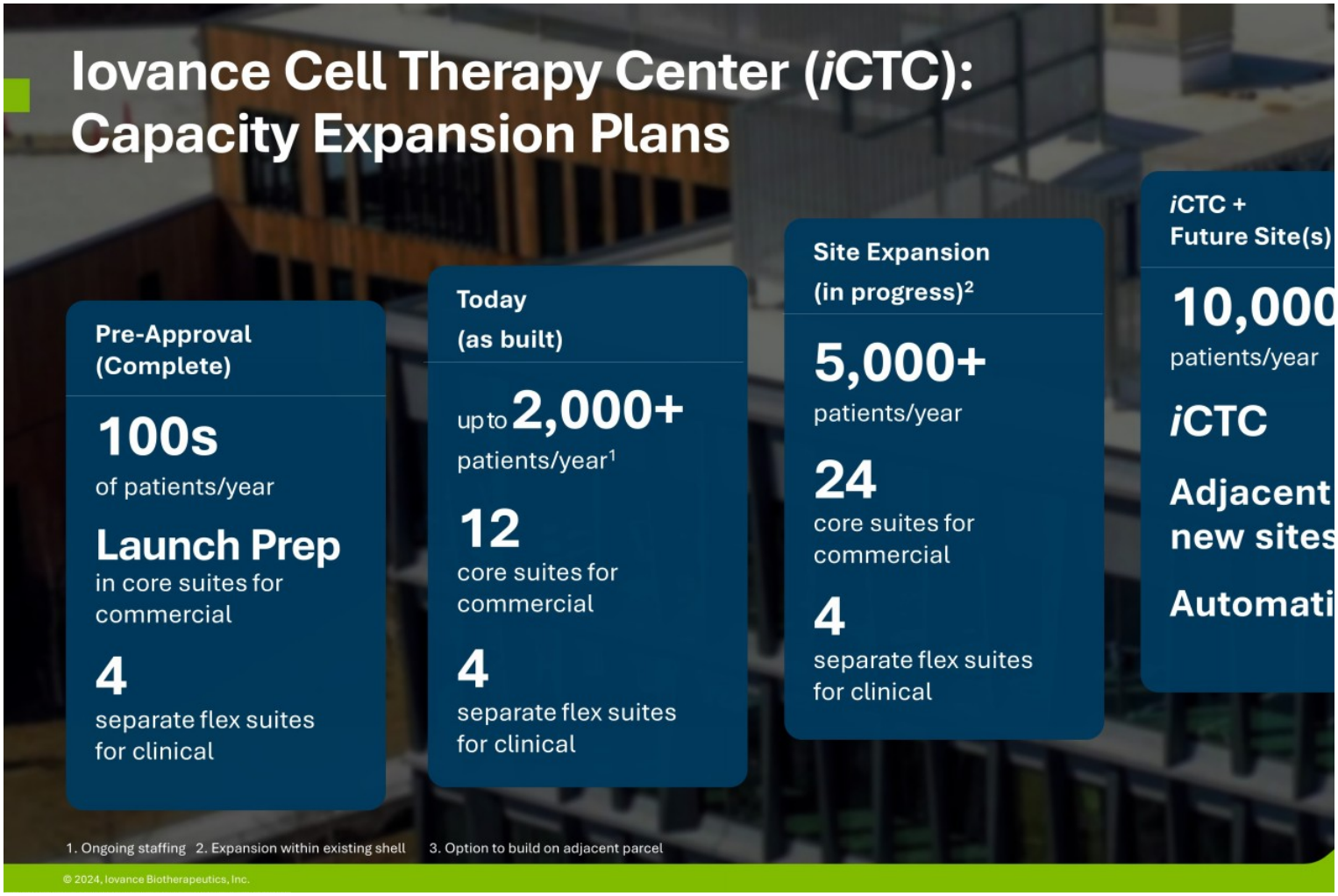
Iovance Cell Therapy Center: *i*CTC

- Built-to-suit custom facility in Navy Yard Philadelphia
- Annual capacity for up to several thousand patients as built
- Expansion underway for additional capacity within iCTC over next few years
- Additional CDMO capacity
- Control to optimize capacity, quality & COGS

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

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 + Future Site(s)
10,000
patients/year
iCTC
Adjacent new sites
Automati
1. Ongoing staffing 2. Expansion within existing shell 3. Option to build on adjacent parcel
© 2024, Iovance Biotherapeutics, Inc.

Proleukin® (aldesleukin) Strategic Benefits

Global Rights Acquired in May of 2023

- Significant revenue anticipated with AMTAGVI™ launch
- IL-2 supply chain secured for AMTAGVI regimen
- Lower clinical trial costs and COGS anticipated

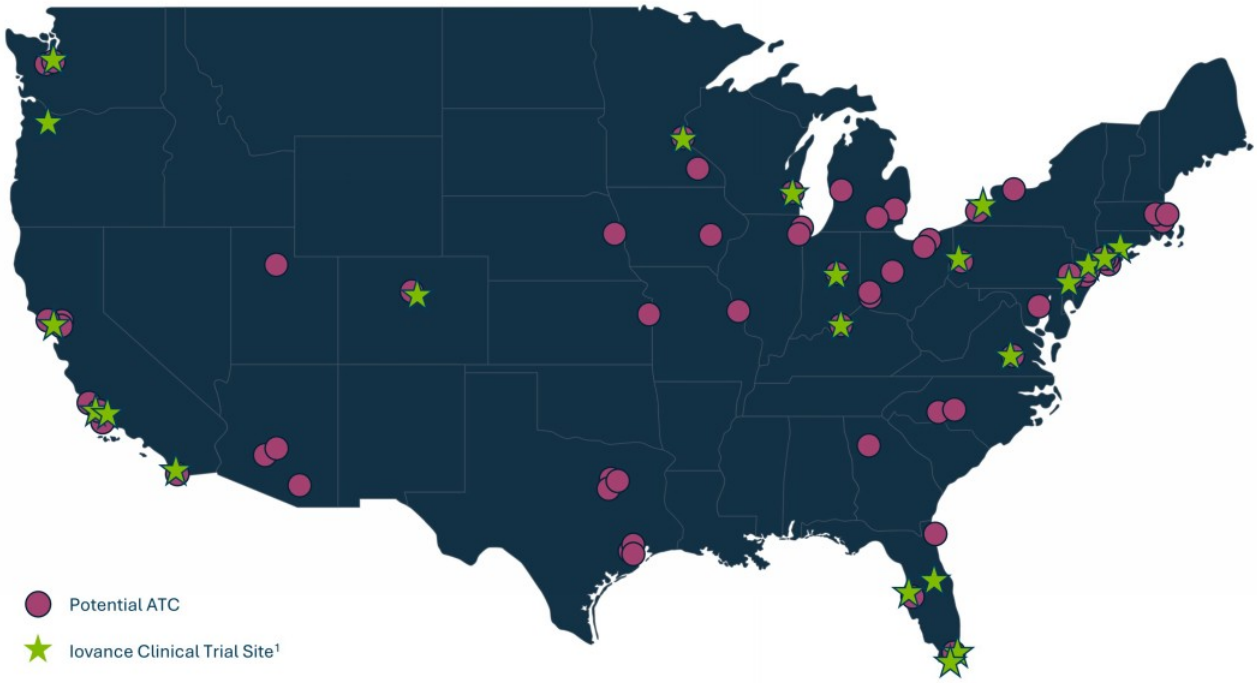
PROLEUKIN®
(aldesleukin) Recombinant IL-2

Short course Pr
administered after
promote T cell grow

Key Transaction
£167.7M
£41.7M

Targeting Potential Authorized Treatment Centers (ATCs)

~30 Active ATCs at Approval; ~50 ATCs Expected 90 Days Post-PDUFA



Targeting
Consider

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

Drive Der

- Top acco
- Commur

1. ClinicalTrials.gov

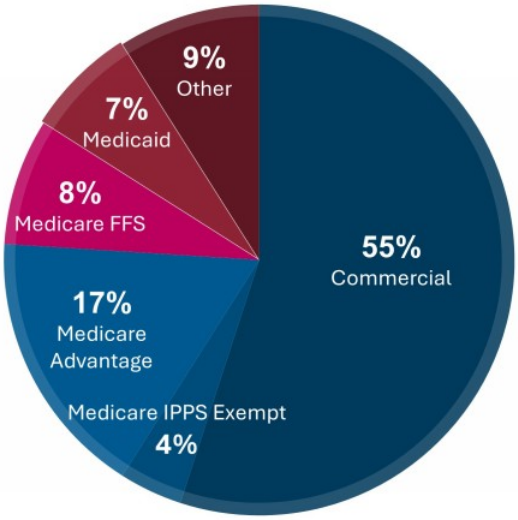
Abbreviations: ATC=Authorized Treatment Centers; NCCN=National Comprehensive Cancer Network; KOL=Key Opinion Leaders; BMT=Bone Marrow Transplant

Market Access

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

Metastatic Melanoma Payer Mix[1]

All Treatment Settings and Lines of Therapy

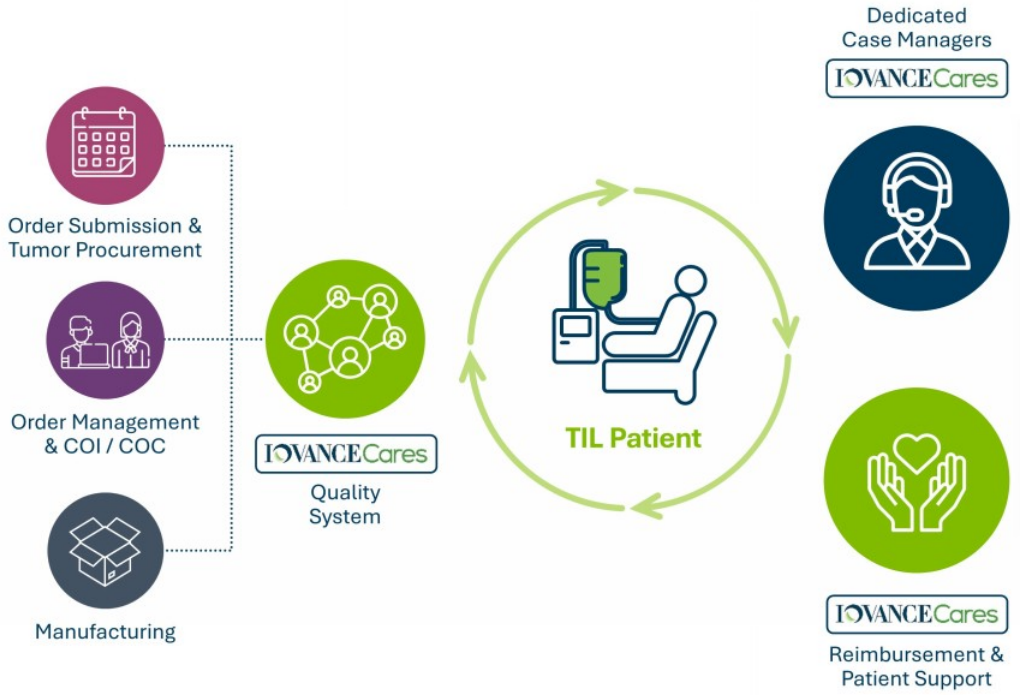


Anticipated Access

- Engagement with payers respo
  ~90% of covered lives
- Strong hospital reimbursement
  - Inpatient payment methodolog
    established
  - Key payers expected to reimbu
    provider costs
- Expect similar coverage to C

1. Metastatic Melanoma Insurance Claims Analysis, TIL-eligible patients treated in the ATC setting(1/1/2018–6/30/2021). Medicaid is 6% Medicaid Advantage and 1% Medicaid Fee-For-Service;
For the 12% Medicare FFS lives, 11 PPS-exempt hospitals are reimbursed by Medicare FFS on a cost-basis (~4%), with the remaining Medicare FFS lives (~8%) reimbursed under DRG-018 payment methodology, NTAP/Outlier payments may add to the total Medicare reimbursement. Other segment includes cash, self-insured, VA, and other unidentifiable claims.
Abbreviations: FFS=Fee-For-Service; ICD-10 PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; NTAP = New Technology Add-on Payment

Supporting Providers & Patients: IovanceCares™



Customer-Cen

- Patient managen
- Proprietary COI/
- Treatment cente

Patient-Centric

- Dedicated case
- Reimbursement
- Patient support p

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

AMTAGVI™ Expansion Plans in Advanced Mela

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

Expanding AMTAGVI™ launch ex-U.S. to double addressable patient population

Preparing for EU MAA and Additional Ex-U.S. Submissions in 2024

57k

Annual deaths worldwide[1]

15k

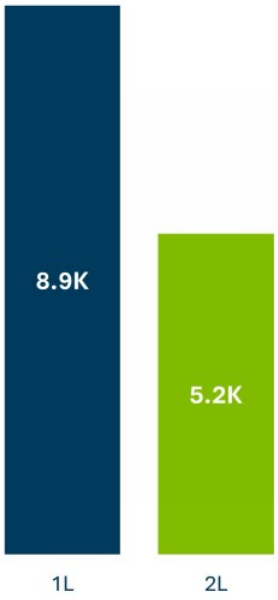
Annual deaths in ex-U.S. target markets[1]

Annual Deaths from Melanoma in Target Ex-U.S. Markets[1]

3.2K	Germany	**1.4K**	Australia
2.8K	UK	**1.2K**	Canada
2.2K	Italy	**1.1K**	Spain
2.1K	France	**0.9K**	Netherlands

Melanoma Drug-Treated

Unresectable / Meta



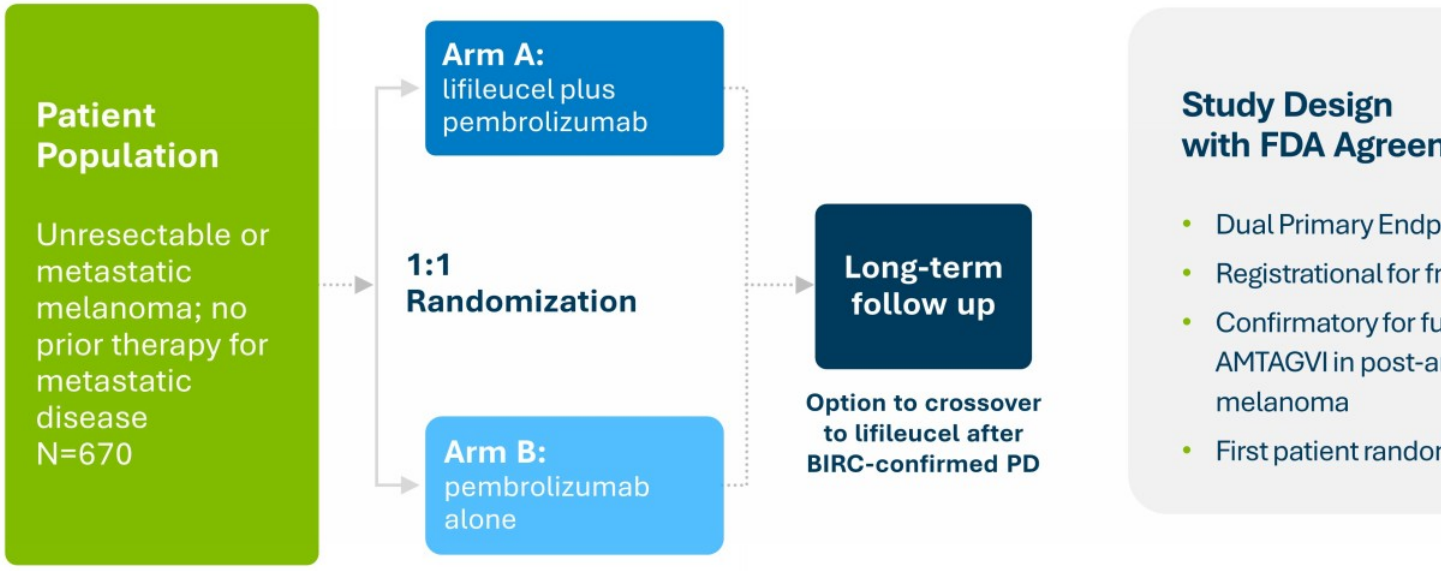
1. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2020
2. Clarivate DRG Disease Landscape (2021)

Abbreviations: EU5=France, Germany, Italy, Spain and United Kingdom; 1L=first line therapy, 2L=second line therapy, 3L=third line therapy, 4L=fourth line therapy;

LIFILEUCEL + PEMBROLIZUMAB IN FRONTLINE ADVANCED MELANOMA

TILVANCE-301 Global Phase 3 and Confirmatory Trial

Randomized, multicenter study with optional crossover to offer all patients potential to receive lifileucel (N



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

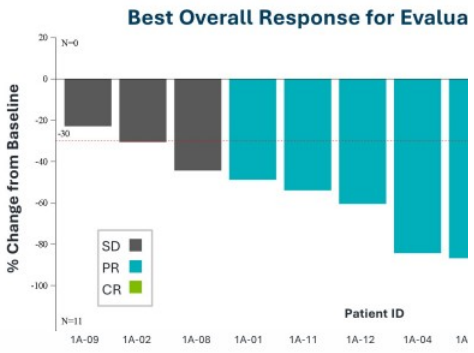
IOV-COM-202 COHORT 1A MELANOMA COMBINATION (TIL+PEMBROLIZUMAB)

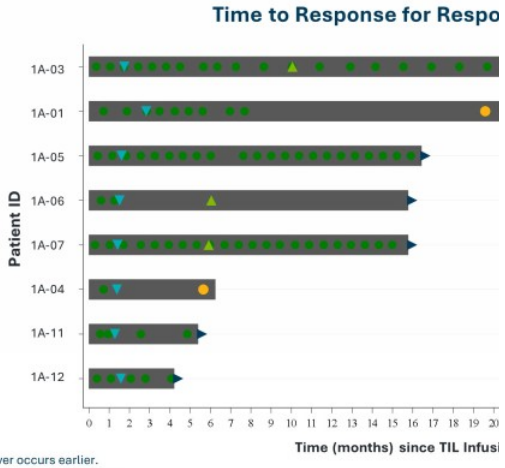
Iovance TIL Clinical Highlights in Combination with Pembrolizumab in Metastatic Melanoma

Lifileucel in combination with anti-PD-1/PD-L1 therapy in ICI-naïve patients
(IOV-COM-202 Cohort 1A, N=12)[1]

66.7% ORR

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





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

Abbreviations: CR=complete response; ICI=immune checkpoint inhibitor; ORR=objective response rate; PR=partial response; SD=stable disease; pembro=pembrolizumab; RECIST=Response Evaluation Criteria in Solid Tumors

TIL Therapy Pipeline

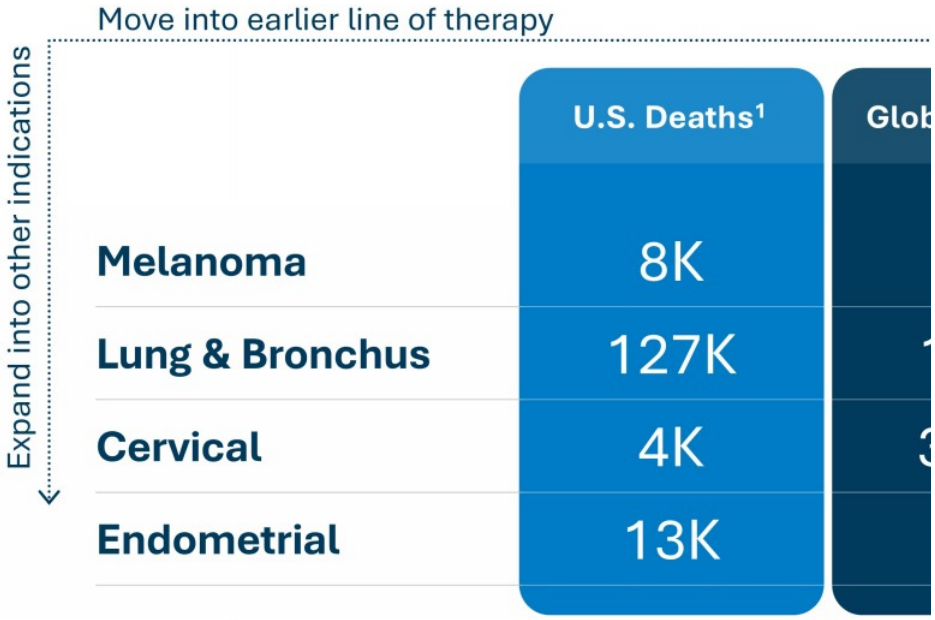
Significant Market Potential in Solid Tumors and our Key Pr

91%

of all cancer cases are solid tumors[1]

1.8M

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



1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. https://seer.cancer.gov accessed February 2024
2. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2020

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

Addressing a Substantial Unmet Need in Metastatic NSCLC

Iovance TIL clinical program:

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

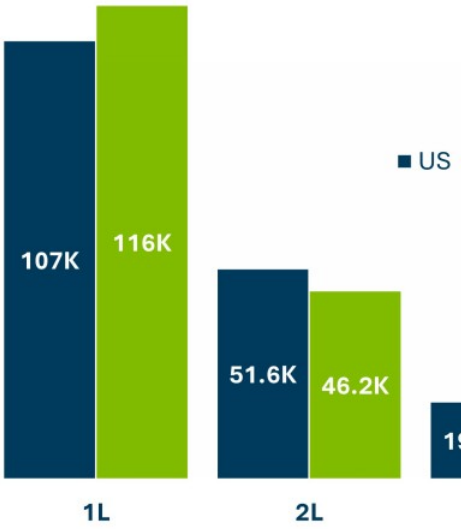
127K annual deaths in U.S.[1]

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

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

NSCLC Drug-Treated Popula

Stage IV (US and EU



1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2023 Estimates. https://seer.cancer.gov accessed February 2024
2. American Cancer Society, Lung Cancer. https://www.cancer.org/cancer/types/lung-cancer/about.html accessed July 2023
3. National Cancer Database, NSCLC survival from >1 million patients assessed. Lou Y et al. Survival trends among non-small-cell lung cancer patients over a decade: impact of initial therapy at academic centers. Cancer Med. 2018.
4. Clarivate DRG Disease Landscape (2021)

Abbreviations: EU5=France, Germany, Italy, Spain and United Kingdom; 1L=first line therapy, 2L=second line therapy, 3L=third line therapy, 4L=fourth line therapy; mOS=median overall survival

IOV-LUN-202 Trial Design

Phase 2 Multicenter Study of LN-145† in Patients Post-Anti-PD-1 NSCLC (NCT04614103)*

Patient Population

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

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

Registrational Cohorts

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

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

Exploratory Cohorts

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

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

Retreatment Cohort

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

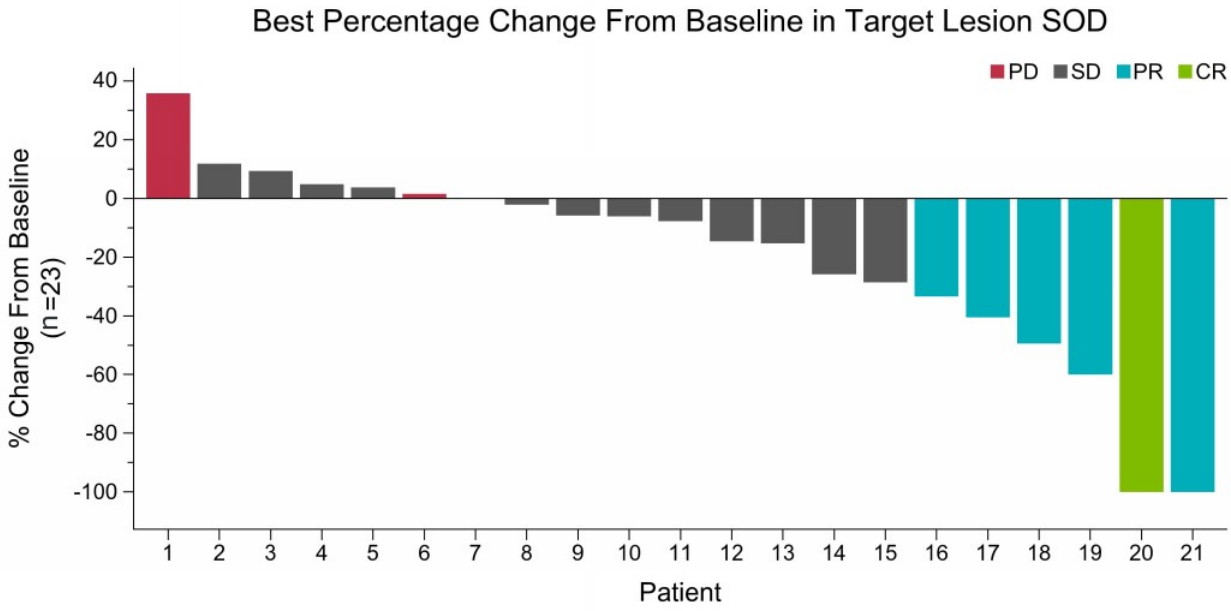
Endpoints

- Primary: ORR by IRC
- Secondary: Safety

* U.S. FDA placed a partial clinical hold on the IOV-LUN-202 trial on December 22, 2023. Enrollment for new patients is paused. Patients previously treated continue to be monitored and followed. Patients who have already undergone tumor resection will continue to receive the LN-145 TIL treatment regimen with additional precautions and risk mitigations..
†Gen 2 TIL product †† Cohort 3 patients unable to undergo surgical harvest, TIL grown from core biopsy
Abbreviations: Anti-PD-1, anti-programmed cell death inhibitor; IRC, independent review committee; NSCLC, non-small-cell lung cancer; ORR, objective response rate; TPS, tumor proportion score

Preliminary Clinical Results for IOV-LUN-202 Cohorts 1 and

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



Data cut: July 6, 2023. 21 evaluable patients for response.
Abbreviations: CR, complete response; NSCLC, non-small-cell lung cancer; PR, partial response; SD=stable disease; SOD, sum of diameters; TPS, tumor proportion score.

Preliminary Clinical Results for IOV-LUN-202 Cohorts 1 and

All Patients Progressed on or After Anti-PD-1 Therapy and Chemotherapy

	Cohort 1 + 2 (n=23)[2]
Objective Response Rate, n (%)[1]	6 (26.1)
(95% CI)	(10.2, 48.4)
Best overall response, n (%)	
CR	1 (4.3)
PR	5 (21.7)
SD	13 (56.5)
PD	2 (8.7)
NE	2 (8.7)

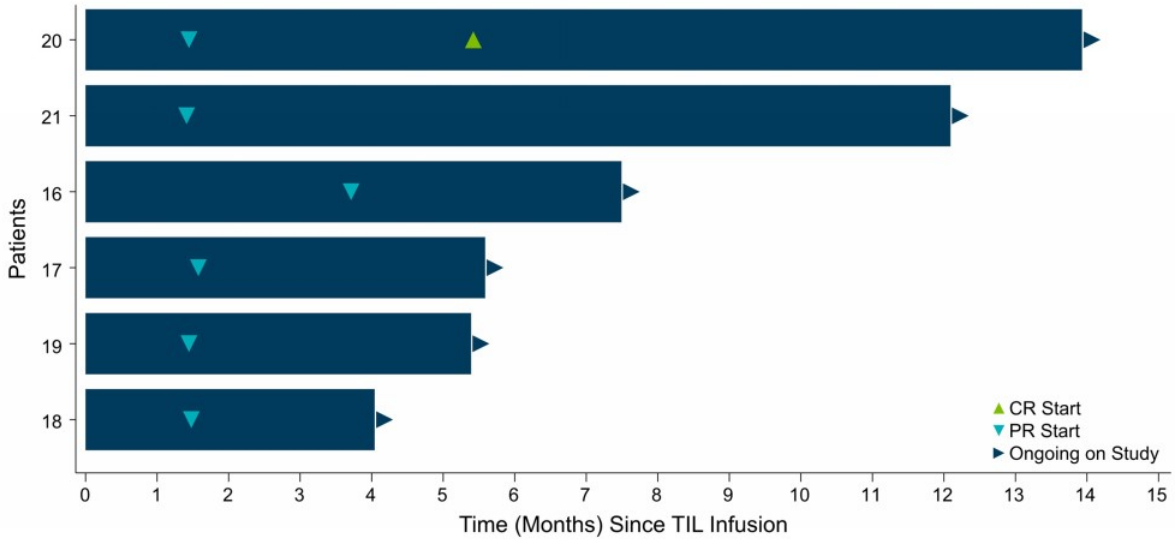
TEAEs were consistent with the underlying disease and known AE profiles of NMA-LD and IL-2

1. Data cut: July 6, 2023. Responses were assessed by investigator.
2. Patients who have progressed on or after chemotherapy and anti-PD-1 therapy for advanced (unresectable or metastatic) NSCLC without EGFR, ROS or ALK genomic mutations and had received at least one line of an FDA-approved targeted therapy if indicated by other actionable tumor mutations.

Abbreviations: AE, adverse event; CI, confidence interval; CR, complete response; ICI, immune checkpoint inhibitor; NE, not evaluable; NMA-LD, non-myeloablative lymphodepletion; NSCLC, non-small-cell lung cancer; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease; TEAE, treatment-emergent AE.

Preliminary Clinical Results for IOV-LUN-202 Cohorts 1 and

All Responses Remain Ongoing at Time of Data Cut



Data cut: July 6, 2023.
A bar is presented for each patient starting from date of LN-145 infusion up to date of new anti-cancer therapy, end of assessment, death, or data cutoff date, whichever occurs earlier.
Abbreviations: CR, complete response; DOR, duration of response; NSCLC, non-small-cell lung cancer; PR, partial response.

Cohort 3A Summary

Proof-of-Concept for TIL in ICI-Naïve NSCLC Regardless of PD-L1 Status

Clinical Activity at 18.2 Months of Follow Up[1]

- Activity across ICI naïve subgroups and TPS Scores
- 58.3% (7/12) ORR and 3 ongoing responses in NSCLC patients with $EGFR^{WT}$ disease
- Safety consistent with Iovance TIL combination studies
- Supports proposed registrational trial design in patients with $EGFR^{WT}$ disease in the frontline setting

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

1. Schoenfeld, et al. WCLC 2023

Abbreviations: cy/flu, cytarabine/fludarabine; EGFR, epidermal growth factor receptor; ICI, immune checkpoint inhibitor; IL-2, interleukin-2; NMA-LD, non-myeloablative lymphodepletion; TPS, tumor proportion score; WT, wild type

Frontline NSCLC Registrational Trial: Design Supported by Cohort

Adding TIL Therapy to Standard-of-Care Therapy

Patient Population

Treatment naïve metastatic NSCLC

EGFR^{WT} Disease

All PD-L1 TPS Scores

SOC Chemo-IO Treatment*

SOC Maintenance Treatment +/- TIL

Long Follo

Experimental Arm

Chemotherapy Platinum Doublet

TIL

Pembrolizumab

Comparator Arm

Chemotherapy Platinum Doublet

Pembrolizumab

- FDA mee discuss be regist treatmer NSCLC p
- Confirma accelera post anti

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

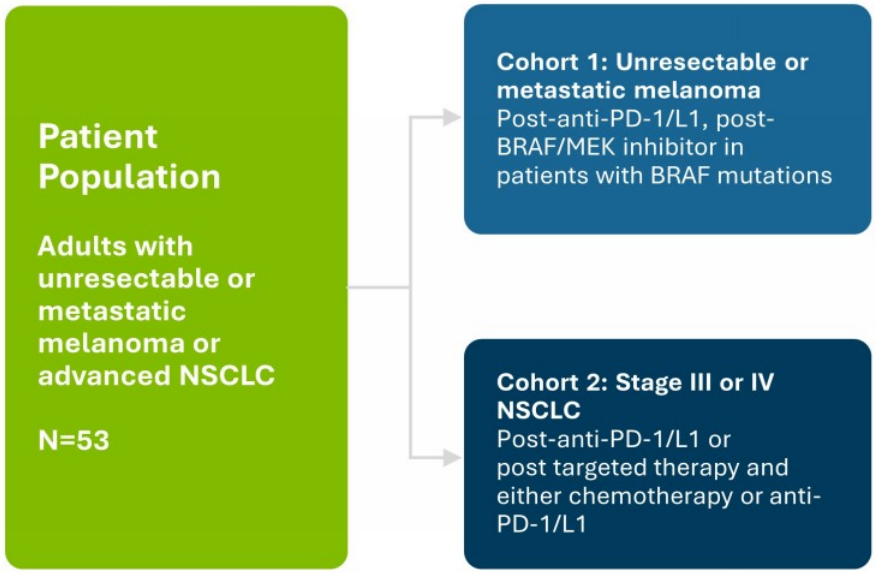
* SOC Chemo-IO is 4-6 cycles of pembro + platinum-based chemotherapy doublet

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

NEXT-GENERATION TIL THERAPY IOV-4001

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

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



Endpoints

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

Study Updates

- 3Q22: first patient treated

NSCLC=non-small-cell lung cancer

Trailblazing Next-Generation TIL Programs

Genetically modify TIL

Cellectis gene-editing TALEN® collaboration[1,2]

PD-1 and other immune checkpoint targets (single and multiple knockouts)

Cytokine-tethered TILs

Optimize TIL composition

PD-1+ selected TIL

CD39/69 double negative TILs[3]

Next-generation processes

Gen 3 (16-day) process

Core biopsy

Exp ne

IO ana from ena

Corporate Summary & Milestones

Well-Capitalized in Pursuit of TIL Commercialization

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

Cash runway is sufficient into 2025*

** Includes anticipated revenue in 2024 from AMTAGVI™ and Proleukin®*

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

Anticipated 2024 Milestones

REGULATORY

- ☑ Obtain FDA approval for lifileucel in advanced melanoma (PDUFA date: February 24, 2024)
- ☐ Submit EMA regulatory dossier (1H24)
- ☐ Submit additional ex-US 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 US and ex-US demand

COMMERCIAL

- ☐ Execute commercial launch (1Q24)
- ☐ On-board 50 ATCs within 90 days of PDUFA date

Corporate Highlights

Pioneering a Transformational Approach to Cure Cancer

Large Market Opportunity in High Unmet Need Cancers

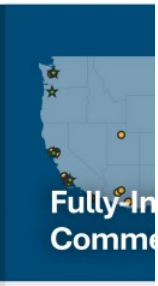
- Initial focus in post-ICI solid tumors
- Expansion into combinations, earlier lines of therapy and genetic modifications
- Key late-stage trials in melanoma, NSCLC and cervical cancer
- First-in-human trial of genetically modified PD-1 inactivated TIL

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 and cervical cancer (BTD)

Efficient and Scalable Proprietary Manufacturing Facility

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



Fully-In Comme

- Experie functio therapy
- TIL serv establis U.S. ca
- Iovance proprie

Abbreviations: BLA, Biologics License Application; BTD, breakthrough therapy designation; FTD, fast track designation; ICI, immune checkpoint inhibitor; NSCLC, non-small cell lung cancer; PD-1, programmed cell death protein-1; RMAT, Regenerative Medicines Advanced Therapy; TIL, tumor infiltrating lymphocytes.