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): June 29, 2021

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.)**
999 Skyway Road, Suite 150 **San Carlos, California**	**94070**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

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

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

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

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

Item 8.01 Other Events.

On June 29, 2021, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing clinical data for its TIL therapy LN-145 in patients with metastatic non-small cell lung cancer who enrolled in Cohort 3B of the Company's ongoing basket study IOV-COM-202. The full text of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

A copy of the slide presentation referred to in the press release is attached hereto as Exhibit 99.2 and 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 June 29, 2021.
99.2	Slide Presentation of Iovance Biotherapeutics, Inc., dated June 29, 2021.
104	Cover Page Interactive Data File - the cover page interactive date file does not appear in the Interactive Date File because its XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

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

Date: June 29, 2021

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Iovance Biotherapeutics Announces Clinical Data for LN-145 in Non-Small Cell Lung Cancer

21.4% Overall Response Rate (ORR) in Relapsed/Refractory Metastatic Non-Small Cell Lung Cancer (mNSCLC) Patients Following One or More Prior Systemic Therapies including Immunotherapy

First Patient Dosed in Registration-Supporting IOV-LUN-202 Study in Second Line mNSCLC

SAN CARLOS, Calif., June 29, 2021 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced clinical data for its tumor infiltrating lymphocyte (TIL) therapy LN-145 in patients with metastatic non-small cell lung cancer (mNSCLC) who enrolled in Cohort 3B of the ongoing basket study IOV-COM-202. Cohort 3B enrolled patients that had progressed on prior immune checkpoint inhibitor (ICI) therapy, including patients with oncogene-driven tumors who received prior tyrosine kinase inhibitor therapy. The initial clinical results are available in a slide presentation on the Iovance website here.

The overall response rate (ORR) by investigator per RECIST 1.1 was 21.4% (n=28, one complete response and five partial responses) and the disease control rate (DCR) was 64.3% following one-time treatment with LN-145 monotherapy, including two responders with PD-L1 negative tumors. Median duration of response was not reached at a median study follow up of 8.2 months. The treatment-emergent adverse event profile was consistent with the underlying disease and known adverse event profiles of non-myeloablative lymphodepletion and IL-2. All patients treated in Cohort 3B received prior anti-PD-1/L1 therapy and all six responding patients also received prior chemotherapy. Historically, ORRs of approximately 20% were reported with ICIs as second-line therapy in ICI-naïve patients who progressed on front-line chemotherapy. Iovance anticipates presenting additional Cohort 3B data at a medical meeting in the second half of 2021.

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated: “There remains a very significant unmet need to increase response rates and prolong survival in the second line non-small cell lung cancer treatment setting. The initial data for LN-145 in this difficult to treat patient population is very promising.”

The Cohort 3B data using Iovance’s TIL cell therapy are the first reported clinical data on TIL administered as a one-time monotherapy in mNSCLC from a prospective, multi-center study, and add significantly to the existing scientific data previously reported by Iovance’s collaborator H. Lee Moffitt Cancer Center.

Iovance also announced today that it dosed the first patient in IOV-LUN-202. Iovance previously opened the IOV-LUN-202 trial to investigate LN-145 in second-line mNSCLC where patients have progressed on one prior ICI and chemotherapy. This trial is designed to be supportive of registration.

Dr. Graf Finckenstein also stated: “We are excited to share our initial results for LN-145 in non-small cell lung cancer, a new potential indication for Iovance TIL cell therapy, which show positive outcomes in patients with high unmet medical need. We see a substantial opportunity to advance LN-145 in the post-ICI setting for patients with lung cancer. These data also have the potential to drive momentum with enrollment in our registration supporting study, IOV-LUN-202, as well as in two additional non-small cell lung cancer cohorts in IOV-COM-202, and we move ahead with great enthusiasm.”

About Iovance Biotherapeutics, Inc.

Iovance aims to improve patient care by making T cell-based immunotherapies broadly accessible for the treatment of patients with solid tumors and blood cancers. Tumor infiltrating lymphocyte (TIL) cell therapy uses a patient's own immune cells to attack cancer. TIL are extracted from a patient's own tumor tissue, expanded through a proprietary process, and infused back into the patient. Upon infusion, TIL reach tumor tissue, where they attack cancer cells. The company has completed dosing in pivotal programs in patients with metastatic melanoma and cervical cancer. In addition, the company's TIL cell therapy is being investigated in a registration-supporting study for the treatment of patients with locally advanced, recurrent or metastatic non-small cell lung cancer (NSCLC). Clinical studies are also underway to evaluate TIL in earlier stage cancers in combination with currently approved treatments, and to investigate Iovance peripheral blood lymphocyte (PBL) T cell therapy for blood cancers. 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 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 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 effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA approval; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials may not be reflected in the final analyses of our ongoing or subsequent clinical trials or subgroups within these trials; 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 new version of the protocol which further defines the patient population to include more advanced patients in our cervical cancer trial may have an adverse effect on the results reported to date; 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 or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk that unanticipated expenses may decrease our estimated cash balances and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

CONTACTS

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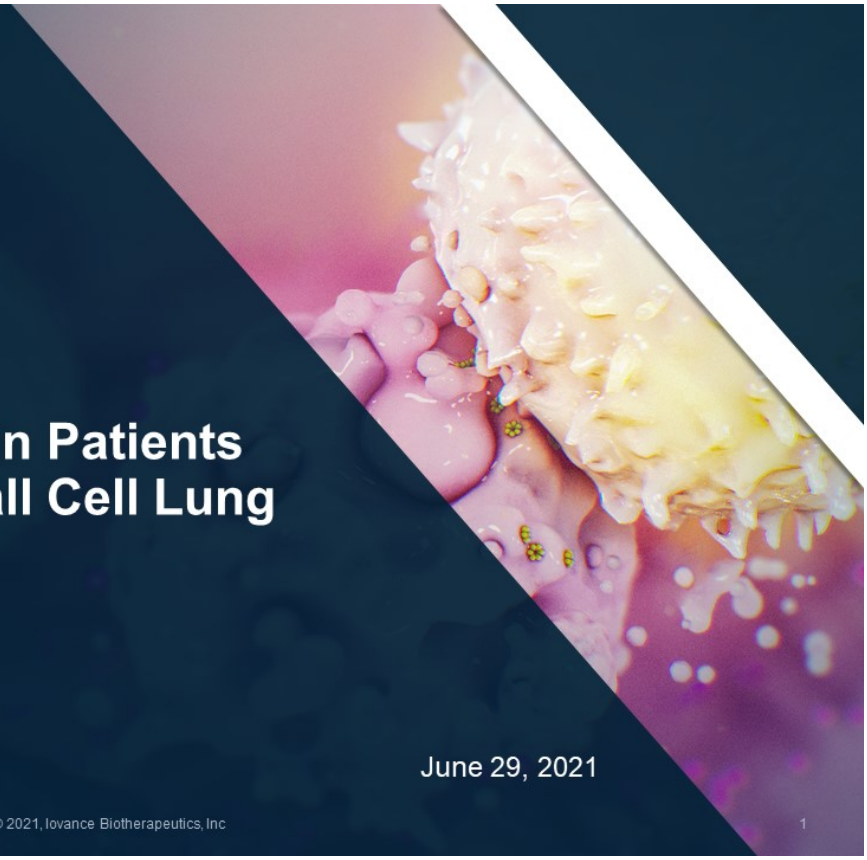
ADVANCING IMMUNO-ONCOLOGY

IOV-COM-202 Cohort 3B: Clinical Data for LN-145 in Patients with Metastatic Non-Small Cell Lung Cancer



June 29, 2021

21.4% ORR for LN-145 in Previously Treated Patients with mNSCLC

- After a median study follow-up of 8.2 months, median DOR was not reached
- 24/28 patients (85.7%), including all responders, had received ≥2 prior lines of systemic therapy
  - All patients received prior anti−PD-1/ anti−PD-L1 therapy and all responders also received prior chemotherapy
- TEAEs were consistent with the underlying disease and known adverse event profiles of non-myeloablative lymphodepletion and IL-2

Response, n (%) [1]	Cohort 3B n=28
Objective Response Rate	**6 (21.4)**
Complete Response [2]	1 (3.6)
Partial Response	5 (17.9)
Stable Disease	12 (42.9)
Progressive Disease	6 (21.4)
Non-Evaluable	4 (14.3)
Disease Control Rate	18 (64.3)
Median Duration of Response	**Not Reached**
Min, Max (months)	1.2+, 20.7+

[1] As assessed by investigator using RECIST 1.1.
[2] One patient is reported as a CR based on a negative FDG-PET scan by investigator.
DOR, duration of response; ICI, immune checkpoint inhibitors; IL-2, interleukin-2; mNSCLC, metastatic non-small cell lung cancer; PD-1, programmed cell death protein-1; PD-L1, programmed death ligand-1; TEAEs, treatment-emergent adverse events; TIL, tumor-infiltrating lymphocytes.

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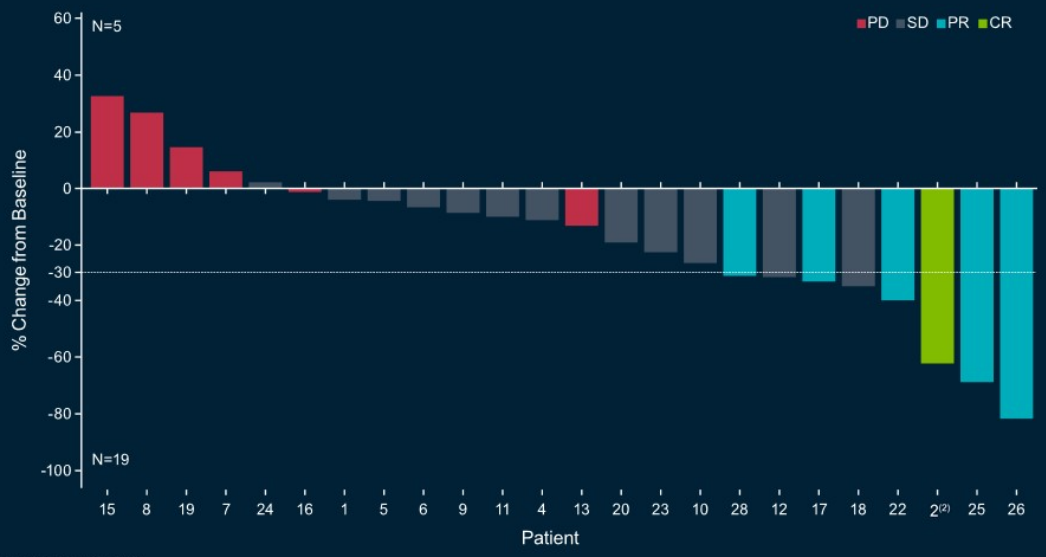
Best Percentage Change from Baseline in Target Lesion Sum of Diameters [1] for Evaluable Patients (n=24)



[1] As assessed by investigator using RECIST 1.1.
[2] Patient 2 is reported as a CR based on a negative FDG-PET scan by investigator.
CR, complete response; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

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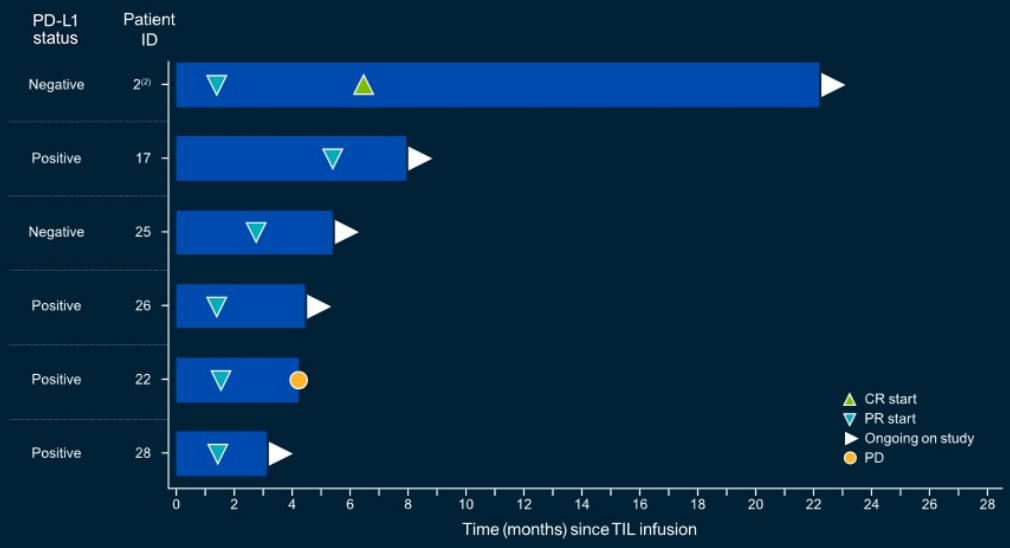
Time to Response [1] for Confirmed Responders (PR or Better; n=6)



[1] As assessed by investigator using RECIST 1.1.
[2] Patient 2 is reported as a CR based on a negative FDG-PET scan by investigator.
CR, complete response; PD, progressive disease; PD-L1, programmed death ligand-1; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; TIL, tumor-infiltrating lymphocytes.

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IOV-COM-202 Cohort 3B: Summary of Data in NSCLC

- Treatment options are limited for patients with metastatic NSCLC who progress or relapse after standard-of-care front-line therapies, including platinum-doublet chemotherapy and ICI or TKI
- In 28 patients with advanced or metastatic NSCLC who progressed after systemic therapy (including ICI or targeted therapy for those with actionable oncogene-driven tumors), LN-145 resulted in:
  - **21.4% ORR** (1 CR and 5 PRs)
  - **Median DOR not reached** at 8.2 months of median study follow up
- The safety profile was consistent with the underlying disease and known adverse event profiles of non-myeloablative lymphodepletion and IL-2
- These results are encouraging and warrant continued investigation of LN-145 TIL cell therapy in patients with advanced or metastatic NSCLC in ongoing trials
  - IOV-COM-202 (NCT03645928) Cohorts 3A and 3C
  - IOV-LUN-202 (NCT04614103)
- Updated data will be presented at a future meeting

CR, complete response; DOR, duration of response; ICI, immune checkpoint inhibitors; IL-2, interleukin-2; NSCLC, non-small cell lung cancer; ORR, objective response rate; PR, partial response; TIL, tumor-infiltrating lymphocytes; TKI, tyrosine kinase inhibitors.

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IOV-COM-202 Cohort 3B: Background

- Nearly 70% of patients with NSCLC present with locally advanced or metastatic disease at the time of diagnosis [1]
- LN-145, an autologous TIL cell therapy, is being investigated (IOV-COM-202, NCT03645928) for the treatment of patients with locally advanced or metastatic NSCLC
  - Patients must have previously received treatment with ICI as part of 1–3 prior lines of systemic therapy, except for patients with actionable oncogene-driven tumors, who must have progressed on ≥1 line of targeted therapy

[1] Molina JR, et al. *Mayo Clin Proc*. 2008;83(5):584-94.
ICI, immune checkpoint inhibitors; NSCLC, non-small cell lung cancer; TIL, tumor-infiltrating lymphocytes.

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