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): October 14, 2020

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 share	IOVA	The Nasdaq Stock Market, LLC

Item 8.01 Other Events.

On October 14, 2020, a copy of an abstract submitted by Iovance Biotherapeutics, Inc. (the "Company") and its collaborators and accepted for presentation at the Society for Immunotherapy in Cancer ("SITC") annual meeting scheduled for November 9, 2020 to November 14, 2020 was inadvertently published by SITC on its website for a limited period of time, in violation of SITC's disclosure embargo, which was intended to run until 8 a.m. Eastern time on November 9, 2020. The abstract is entitled "Safety and efficacy of tumor infiltrating lymphocytes (TIL; LN-145) in combination with pembrolizumab for advanced, recurrent or metastatic HNSCC" and includes results of an ongoing clinical study sponsored by the Company. As a precautionary measure, the Company is providing a copy of the abstract to the wider investment community. The full text of the abstract is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Abstract entitled Safety and efficacy of tumor infiltrating lymphocytes (TIL; LN-145) in combination with pembrolizumab for advanced, recurrent or metastatic HNSCC

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: October 14, 2020

IOVANCE BIOTHERAPEUTICS, INC.

By: /s/ MARIA FARDIS
Maria Fardis, Chief Executive Officer

Exhibit 99.1

Title

Safety and efficacy of tumor infiltrating lymphocytes (TIL; LN-145) in combination with pembrolizumab for advanced, recurrent or metastatic HNSCC

Authors

A. Jimeno, S. Papa, M. Haigentz, J. Moreno, J. Schardt, M. Fardis, F. Graf Finckenstein, R. Fiaz, G. Chen, A. Cacovean, Z. Goldberg and A. Sukari

Background

Single agent checkpoint inhibitors (CPI) are an approved first or second-line therapy in head and neck squamous cell carcinoma (HNSCC), but their efficacy is limited. Adoptive cell therapy with tumor infiltrating lymphocytes (TIL; LN-145) has demonstrated efficacy in multiple malignancies alone or in combination with CPI. To improve HNSCC therapy, a combination of pembrolizumab and LN-145 was explored.

Methods

IOV-COM-202 is an ongoing Phase 2 multicenter, multi-cohort, open-label study evaluating LN-145 in multiple settings and indications, and here we report cohort 2A which enrolled CPI naïve HNSCC patients who received the combination of LN-145 and pembrolizumab. Key eligibility criteria include up to 3 lines of prior therapy, ECOG $\leq$1, at least one resectable metastasis for LN-145 production, and at least another measurable lesion after tumor resection. Primary endpoints are ORR per RECIST v1.1 by investigator and safety as measured by the incidence of grade $\geq$ 3 treatment-emergent adverse events (TEAEs). LN-145 production method uses central GMP manufacturing in a 22-day process yielding a cryopreserved TIL product (figure 1). Preconditioning chemotherapy consists of cyclophosphamide/fludarabine, followed by LN-145, and then $\leq$ 6 doses of IL-2 over $\leq$3 days. Pembrolizumab is initiated post-tumor harvest but prior to LN-145 and continues after LN-145 infusion Q3W until toxicity or progression (figure 2).

Results

Nine (N=9) HNSCC patients have received LN-145 plus pembrolizumab, with a median duration of follow up of 6.9 months. Nine and 8 patients were evaluable for safety and efficacy, respectively. Mean number of prior therapies was 1.1 with 89% of the patients having received prior chemotherapy. Four were HPV+, 2 HPV-, 3 unknown. The Treatment Emergent Adverse Event (TEAE) profile was consistent with the underlying advanced disease and the known AE profiles of pembrolizumab, the lymphodepletion and IL-2 regimens. The most common TEAE were chills, hypotension, anemia, thrombocytopenia, pyrexia, fatigue and tachycardia. Four patients had a confirmed, objective response with an ORR of 44% (1 CR, 3 PR, 4 SD, 1 NE) per RECIST 1.1. The disease control rate at data cutoff was 89% in 9 patients, and 7 of the 8 evaluable patients (87.5%) had a reduction in target lesions. Median DOR was not reached.

Conclusions

LN-145 can be safely combined with pembrolizumab in patients with metastatic HNSCC. LN-145 plus pembrolizumab shows early signs of improved efficacy particularly when compared with literature reports of pembrolizumab alone in a comparable patient population. Enrollment is ongoing and updated data will be presented.

Clinical trial information: NCT03645928

Figure 1: Iovance TIL Production

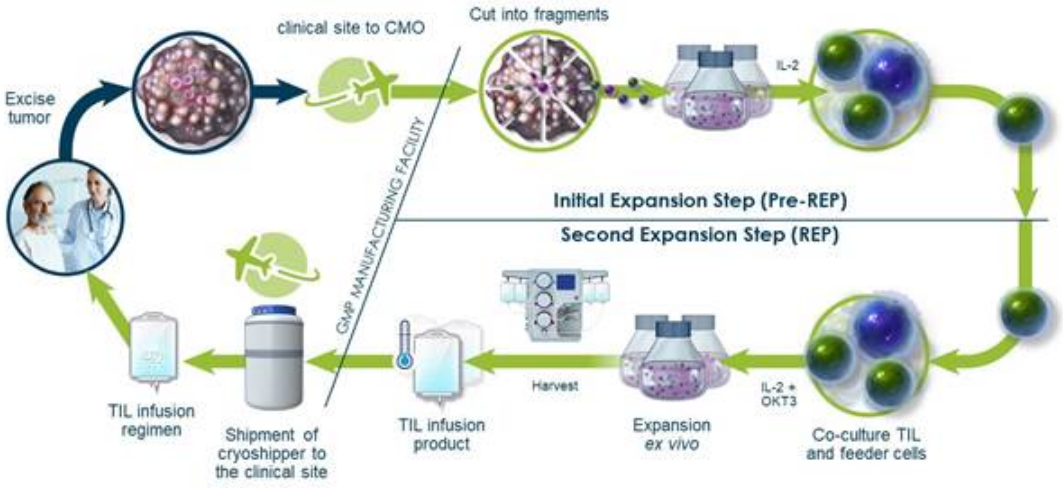
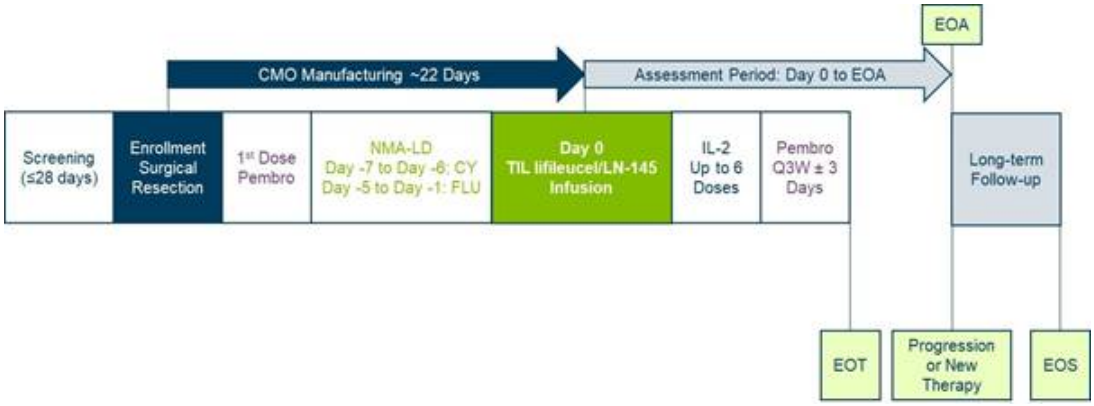


Figure 2: Study Schema



Abbreviations: Cy=cyclophosphamide; EOA=end-of-assessment; EOS=end-of-study; EOT=end-of-treatment; Flu=fludarabine; IL-2=interleukin-2; NMA-LD=nonmyeloablative lymphodepletion; Q3W=every 3 weeks; TIL=tumor infiltrating lymphocytes.