Trial in Progress: A Phase 2, multicenter study of autologous tumor infiltrating lymphocytes (TIL, LN-145) cell therapy in patients with metastatic non-small cell lung cancer (IOV-LUN-202)

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Background
- Adoptive cell transfer (ACT) using autologous tumor-infiltrating lymphocytes (TIL) has been shown to be efficacious for the treatment of advanced metastatic melanoma, and other solid tumors with high tumor mutational burden. 1, 2
- IOVance TIL cell therapy (LN-145 [efficacy]) and LN-145, has demonstrated efficacy and safety in clinical trials for several high unmet medical need patient populations, specifically unresectable and metastatic melanoma, in resected, refractory or persistent cervical cancer, and in head and neck squamous cell carcinoma (HNSCC). 3, 4
- Further, TIL cell therapy has shown efficacy in metastatic non-small cell lung cancer (mNSCLC) in a Phase 1 study in combination with rivaroxaban. 5

IOV-LUN-202
- The IOV-LUN-202 (NCT04614993) clinical trial is evaluating IOVance TIL cell therapy with LN-145 in patients with mNSCLC without actionable driver mutation(s), who have progressed on or following a single line of approved systemic therapy consisting of combined immune checkpoint inhibitors (ICIs) + chemotherapy ± bevacizumab.

IOvance TIL Manufacturing
- The one-day LN-145 manufacturing process requires procurement of a small 1.5 cm sample of tumor tissue, which is shipped to a central manufacturing facility, where outside of the suppressive tumor microenvironment the TIL are reinvigorated and expanded to approximately 10^10-10^11 cells.
- LN-145 manufacturing is a 16-22 day process.

Study Overview & Endpoints
- A total number of approximately 95 patients are planned to be infused with LN-145 in Cohorts 1, 2, and 3.
- Primary endpoint:
  - Efficacy: Objective response rate (ORR) per RECIST 1.1 as assessed by IRC (Cohort 1 and Cohort 2) or by investigator (Cohort 3 and Cohort 4).
- Secondary endpoints:
  - Safety and additional efficacy parameters.
  - Efficiency of generating LN-145 from tumor core biopsies (Cohort 3).
- Exploratory endpoints:
  - Analyses of predictive and pharmacodynamic biomarkers of clinical activity of LN-145.

Study Cohorts

Cohort 1
- N = 40
- TPS <1% prior to CPI
- Unresectable, or metastatic, driver mutation negative NSCLC who have disease progression on one prior ICI + chemotherapy (N=95)
- Patients with unresectable, or metastatic, driver mutation negative NSCLC who have disease progression on one prior ICI + chemotherapy

Cohort 2
- N = 40
- TPS ≥1% prior to CPI
- Unresectable, or metastatic, driver mutation negative NSCLC who have disease progression on one prior ICI + chemotherapy

Cohort 3
- N = 15
- TPS <1% prior to CPI and unable to safely undergo surgical tissue procurement
- Unresectable or metastatic, driver mutation positive NSCLC who have disease progression on one prior ICI + chemotherapy

Cohort 4
- Infusion (previously treated with LN-145 in Cohorts 1, 2 or 3)

References:

Disclosures:
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