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

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Introduction

Background
• Single agent immune checkpoint inhibitors (ICIs) are an approved first or second-line therapy in head and neck squamous cell carcinomas (HNSCC), however their efficacy is limited.1
• Adoptive cell therapy utilizing tumor infiltrating lymphocytes (TIL; LN-145) leverages and enhances the body’s natural defense against cancer.
• Iovance autologous TIL immunotherapy cell product (Lifileucel®/LN-145, single manufacturing) has demonstrated efficacy in metastatic melanoma and cervical carcinoma.2
• To date, all LN-145 blockade naïve patients, a combination of pembrolizumab and LN-145 was explored.

Methods
• Patients enrolled in the IOV-207 (NCT03455326) is an ongoing Phase 2 multicenter, open-label study evaluating LN-145 in multiple settings and indications, and here we report on Cohort 2A:
  - Involuntary-agent autologous (LN-145)
  - Patient population: (ICP/CRC)
  - Study regimen: LN-145 and pembrolizumab
  - Manufacturing method central manufacturing of cryopreserved TIL, 62-day duration

Results

Table 1. Patient Characteristics

Table 2. Treatment Emergent Adverse Events (%)

Figure 1. LN-145 Production Method Uses Central GMP Manufacturing in a 22-day Process Yielding a Cryopreserved TIL Product

Figure 2. Study Schema

Figure 3. Adverse Events Over Time

Figure 4. Time to Response for Evaluable Patients (PR or Better)

Figure 5. Percent Change from Baseline in Sum of Target Lesion Diameters Over Time

Conclusions
• Metastatic HNSCC presents a high unmet medical need with low survival rates and with limited durable treatment options.
• The Treatment Emergent Adverse Event profile of the combination therapy was consistent with the underlying advanced disease and the known AE profiles of pembrolizumab, lymphodepletion and KL-2 regimens.
• Efficacy for 9 HNSCC patients treated with pembrolizumab + therapy: pembrolizumab
  - 11.1% CR
  - 44.4% ORR
  - 88.9% DCR
• At median follow up of 9.5 months, the median DOR has not been reached.

References
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Acknowledgement
This study and poster are sponsored by Iovance Biotherapeutics, Inc.

The authors would like to thank the patients and their families for participation in the study.

The authors would also like to acknowledge the support and dedication of all site team members from all the clinical trial sites.

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Endpoint
• Objective Response Rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST v1.1) is assessed by investigator.

Methods
• Data extract as of 16 Oct 2020 for Cohort 2A.
• Cohort 2A Safety & Efficacy Rate: 9 patients who underwent reaction for the purpose of TIL generation and received LN-145 infusion as well as one dose of pembrolizumab, and could have had at least 1 efficacy evaluation as of the data extraction date.

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