A Phase 2 study of autologous tumor infiltrating lymphocytes (TIL; lifileucel [LN-144]/LN-145) in patients with solid tumors

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BACKGROUND

• Metastatic melanoma, head and neck squamous cell carcinoma (HNSCC), and non-small cell lung cancer (NSCLC) are prevalent solid tumors with a combined incidence of 389,000+ and 177,000+ deaths worldwide annually
• Although initial treatment may provide an initial response, duration of response (DOR) is generally short and OS is poor5-7
• Tumor infiltrating lymphocytes (TIL) have demonstrated durable complete responses in immunogenic tumors with high mutational burden; the presence of TIL in tumor specimens has been correlated with patient outcome8-10
• Pembrolizumab may support trafficking into the tumor prior to and may enhance expansion and efficacy post-TIL infusion by dampening TME suppressor mechanisms12-14
• This study was designed to evaluate the efficacy and safety of lifileucel and LN-145 either alone or in combination with pembrolizumab in patients with solid tumors

Fig 1. Iovance Cryopreserved lifileucel & LN-145 Manufacturing Process

Manufacturing process results in TIL infusion product of polyclonal autologous TIL cells

STUDY DESIGN

Figure 2. A Phase 2, Multicenter Study of Autologous Tumor Infiltrating Lymphocytes (TIL) or LN-145 in Patients with Solid Tumors (NCT03645928)

STUDY FLOWCHART

IOV-COM-202 STUDY OBJECTIVES

Primary:
• Objective response rate (ORR) per RECIST 1.1
• Safety evaluation

Secondary:
• Duration of response (DOR), disease control rate (DCR), progression free survival (PFS)
• Complete response (CR) rate and Overall Survival (OS)

* Primary and secondary objective results will be analyzed independently for each cohort

MAJOR INCLUSION & EXCLUSION CRITERIA

Key Inclusion Criteria
• Histologically/cytologically confirmed diagnosis of:
  – Cohort 1: Stage IIIIC IV melanoma
  – Cohort 2: unresectable, recurrent or metastatic HNSCC
  – Cohort 3: Stage III or Stage IV NSCLC
• At least 1 tumor lesion resectable for TIL generation
• A remaining lesion measurable for RECIST 1.1/irRECIST response assessment
• 18 years or older
• ECOG performance status 0 or 1
• Adequate bone marrow and organ function

Key Exclusion Criteria
• Prior cell therapy
• Symptomatic and/or untreated brain metastases
• Prior immunotherapy for combination cohorts
• Active or prior documented autoimmune or inflammatory disorders or active infections
• Primary or acquired immunodeficiency
• History of hypersensitivity to any components of TIL therapy
• LVEF < 45% or NYHA Class II or higher
• History of obstructive or restrictive pulmonary disease
• History of other malignancies, except for curatively treated with no evidence of disease for ≥ 3 years

SUMMARY

• Advanced solid tumors in patients with Melanoma, HNSCC and NSCLC represent a high unmet medical need with low survival rates and limited effective treatment options
• The presence of TIL has been correlated with improved outcomes in a number of solid tumors
• TIL have demonstrated efficacy in multiple solid tumors resulting in durable long-term response
• This study aims to assess lifileucel and LN-145 as first-line combination therapy with pembrolizumab for patients with Melanoma, HNSCC, and either alone or in combination for the treatment of patients with NSCLC
• For patients with multiple solid tumors, TIL may provide durable tumor control with a single treatment

Disclosure
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References