Autologous LN-145 in Patients With Metastatic Non-Small-Cell Lung Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 70 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients who are over 70 years of age may be allowed to enroll after discussion with the Medical Monitor. * Have historically or pathologically confirmed diagnosis of metastatic Stage IV NSCLC without EGFR, ALK, or ROS1 genomic alterations. * For patients who have actionable mutations (other than EGFR, ALK, or ROS1 genomic alterations), 1 additional line of therapy with the appropriate health authority approved targeted therapy is required. * Patients must have documented radiographic disease progression on or after the first-line therapy, including concurrent or sequential ICI and platinum-based chemotherapy ± bevacizumab. No more than 1 prior line is allowed if ICI and platinum-based chemotherapy were administered concurrently and no more than 2 prior lines are allowed for sequential administration of platinum-based chemotherapy and ICI as 2 separate lines. * LN-145 manufacture is allowed for patients who have residual resectable disease after completion of the platinum-based chemotherapy component of the front-line ICI and platinum-based chemotherapy combination and meet all eligibility criteria except documented disease progression. These patients must intend to receive TIL therapy after disease progression * Prior systemic therapy in the adjuvant or neoadjuvant setting, or as part of definitive chemoradiotherapy, will count as a line of therapy if the patient had disease progression during or within 12 months after the completion of such therapy. * At least 1 resectable lesion for TIL production and at least one remaining measurable lesion, as defined by RECIST v1.1 * Have adequate organ function * LVEF \> 45%, NYHA Class 1 * Have adequate pulmonary function * ECOG performance status of 0 or 1 * Patients of childbearing potential or those with partners of childbearing potential must be willing to practice an approved method of highly effective birth control during treatment and up to 12 months after all protocol-related therapy

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Exclusion Criteria:

* Patients who have EGFR, ALK or ROS1 driver mutations * Patients who have symptomatic, untreated brain metastases. * Patients who have had allogeneic organ transplant or prior cell therapy within the past 20 years * Patients who have any form of primary immunodeficiency * Patients who are on systemic steroid therapy ≥ 10 mg/day of prednisone or equivalent. * Patients who have received a live or attenuated vaccination within 28 days prior to the start of treatment * Patients who have had another primary malignancy within the previous 3 years * Participation in another interventional clinical study within 21 days

Conditions & Interventions

Interventions:
BIOLOGICAL: LN-145, BIOLOGICAL: LN-145
Conditions:
Metastatic Non Small Cell Lung Cancer
Keywords:
LN-145, Cell Therapy, Autologous Adoptive Cell Therapy, Cellular Immuno-therapy, Tumor Infiltrating Lymphocytes, TIL, IL-2, Non Small Cell Lung Cancer, NSCLC, Second line Lung Cancer, Bronchial Neoplasms, Carcinoma, Lung Disease, Metastatic Lung Cancer, Metastatic Non Small Cell Lung Cancer, Metastatic NSCLC, Lung Carcinoma, PD-L1, Stage IV Lung Cancer, Stage IV Non-Small Cell Lung Cancer, Stage IV NSCLC, Systemic Therapy, 2nd line therapy, Second line therapy, CPI, Immune checkpoint inhibitor (ICI), NSCLC Recurrent, Recurrent Lung Cancer, Recurrent Lung Carcinoma

More Information

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System ID: NCT04614103

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