Study to Investigate Lifileucel Regimen Plus Pembrolizumab Compared With Pembrolizumab Alone in Participants With Untreated Advanced Melanoma.

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 70 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Participant has a histologically or pathologically confirmed diagnosis of Stage IIIC, IIID, or IV unresectable or metastatic melanoma. 2. In the investigator's assessment, the participant has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and an estimated life expectancy of \> 6 months. 3. Participant is assessed as having at least one resectable lesion (or aggregate lesions) for lifileucel generation. 4. Participant must have at least one measurable disease as defined by RECIST 1.1 following tumor resection. 5. Participants must have adequate organ function. 6. Participants of childbearing potential or those with partners of childbearing potential must be willing to practice an approved method of highly effective birth control. 7. Participants who are \> 70 years of age may be allowed to enroll after the investigator discusses with the medical monitor.

Exclusion Criteria:

1. Participant has melanoma of uveal/ocular origin. 2. Participant has symptomatic untreated brain metastases. 3. Participant received more than 1 prior line of therapy. 4. Participant received prior therapy for metastatic disease 5. Participants with a BRAF V600 mutation-positive tumor received prior adjuvant/neoadjuvant ICI therapy only 6. Participant has an active medical illness(es) that, in the opinion of the investigator, would pose increased risks for study participation, such as systemic infections; seizure disorders; coagulation disorders; or other active major medical illnesses of the cardiovascular, respiratory, or immune systems. 7. Participant has any form of primary or acquired immunodeficiency (eg, SCID or AIDS). 8. Participant had another primary malignancy within the previous 3 years (except for those that do not require treatment or were curatively treated \>1 year ago, and in the judgment of the investigator do not pose a significant risk of recurrence.) 9. Participant has a history of allogeneic cell or organ transplant. Other protocol defined inclusion/exclusion criteria could apply.

Conditions & Interventions

Interventions:
BIOLOGICAL: Lifileucel plus Pembrolizumab, BIOLOGICAL: Pembrolizumab with Optional Crossover Period
Conditions:
Metastatic Melanoma, Unresectable Melanoma, Melanoma
Keywords:
Tumor Infiltrating Lymphocytes, TIL, Metastatic Melanoma, Unresectable Melanoma, Cell Therapy, Cellular Immuno-therapy, IL-2, Non-myeloablative lymphodepletion (NMALD), Check point inhibitor, Melanoma, Lifileucel, Stage III Melanoma, Stage IV Melanoma, Skin cancer, Skin cancer types, Malignant melanoma, Autologous Adoptive Cell Therapy, Autologous Adoptive Cell Transfer, LN-144, Pembrolizumab, Pembro, Adjuvant/Neo-adjuvant, BRAF/MEK, ICI, BRAF v600, Immune checkpoint inhibitor, Tumor infiltrating T-cells, TILVANCE, TILVANCE-301

More Information

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Phase: PHASE3
IRB
Number:
System ID: NCT05727904
