

A Study With Combinations of Anti-LAG-3 and Anti-PD-1 Antibodies in Adult Participants With Advanced or Metastatic Melanoma (Harmony Head-to-Head)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

1. Participants with histologically confirmed unresectable stage III and stage IV (metastatic) melanoma per American Joint Committee on Cancer (AJCC), eighth revised edition. 2. Participants must not have received prior systemic therapy for unresectable or metastatic melanoma as described in the protocol. 3. Measurable disease per RECIST version 1.1. 4. Eastern Cooperative Oncology Group (ECOG) performance status (PS) ≤ 1 . 5. Adequate bone marrow, hepatic, and kidney function. 6. Known B-Rapidly Accelerated Fibrosarcoma protein (BRAF) V600 mutation status or submitted sample for BRAF V600 mutation assessment as described in the protocol. Key

Exclusion Criteria:

Medical Conditions: 1. Uveal, acral or mucosal melanoma. 2. Ongoing or recent (within 2 years) evidence of an autoimmune disease that required systemic treatment with immunosuppressive agents as described in the protocol. 3. Uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B (HBV), or hepatitis C virus (HCV) infection; or diagnosis of immunodeficiency that is related to, or results in chronic infection. Mild cancer-related immunodeficiency (such as immunodeficiency treated with gamma globulin and without chronic or recurrent infection) is allowed. Prior/Concomitant Therapy: 4. Prior immune checkpoint inhibitor therapy other than anti-PD1/PD-L1 as described in the protocol. 5. Systemic immune suppression as described in the protocol. Other Comorbidities: 6. Participants with a history of myocarditis. 7. Troponin T (TnT) or troponin I (TnI) $> 2 \times$ institutional upper limit of normal (ULN). 8. Active or untreated brain metastases or spinal cord compression as described in the protocol. Note: Other protocol-defined Inclusion/ Exclusion Criteria apply.

Conditions & Interventions

Interventions:

DRUG: fiantlimab, DRUG: cemiplimab, DRUG: relatlimab+nivolumab

Conditions:

Melanoma

Keywords:

Unresectable Melanoma, Metastatic Melanoma, Advanced Melanoma, Stage III, Stage IV

More Information

Contact(s): Clinical Trials Administrator - clinicaltrials@regeneron.com

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06246916

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