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This is a Study to Learn About How the Combination of the Study Medicines Sigvotatug Vedotin Plus Pembrolizumab Works in People With Non-small Cell Lung Cancer With High Levels of PD-L1. (Be6A Lung-02)

Pfizer

Status and phase

Begins enrollment in 2 months Phase 3

Conditions

Carcinoma, Non-Small-Cell Lung (NSCLC)
Carcinoma, Non-Small-Cell Lung
Non-Small Cell Lung Cancer

Treatments

Drug: Pembrolizumab
Drug: Sigvotatug Vedotin

Study type

Interventional

Funder types

Industry

Identifiers

NCT06758401
C5751003

Take notes

View 5 locations

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Timeline

Last updated: Mar 19, 2025

Today
Mar 21, 2025

Start date

View trial history →

Sponsor of this trial

Lead Sponsor

Pfizer

Details and patient eligibility

About

The purpose of the study is to compare how the new combination treatment (Sigvotatug Vedotin plus pembrolizumab) works compared to pembrolizumab alone in patients with non-small cell lung cancer (NSCLC) with high levels of PD-L1. This is a protein that acts as a kind of "brake" to keep the body's immune responses under control.

The study is seeking for participants who:

- Are confirmed to have NSCLC (Stage 3 or 4).
- Have PD-L1 levels in more than 50% of the cancer cells.

All participants in this study will receive pembrolizumab at the study clinic once every 6 weeks as an intravenous (IV) infusion (give directly into a vein). In addition, half of the participants will also receive Sigvotatug Vedotin once every 2 weeks as an IV infusion in addition to receiving pembrolizumab.

Participants may receive pembrolizumab for up to about two years. Those participants taking Sigvotatug Vedotin can continue until their NSCLC is no longer responding. The study team will monitorsee how each participant is doing with the study treatment during regular visits at the clinic.

Hide

Enrollment	Sex
714 estimated patients	All
Ages	**Volunteers**
18+ years old	No Healthy Volunteers

Inclusion criteria

1. Participants must meet the following criteria:
    1. Have pathologically confirmed Stage IIIB or IIIC NSCLC and not be a candidate for surgical resection or definitive chemoradiation, or Stage IV NSCLC per the AJCC Staging Manual (Version 8.0) and the UICC Staging System (Eighth edition).

4. Large cell neuroendocrine carcinoma is excluded.
5. Candidate for treatment with pembrolizumab monotherapy per local guidelines.

2. Tumor has PD-L1 expression in ≥50% of tumor cells (TPS ≥50%) as determined by local testing
3. Measurable disease based on RECIST v1.1 per investigator.
4. Resolution of acute effects of any prior therapy to either baseline severity or NCI CTCAE Grade 1 or less (except for AEs not constituting a safety risk in the investigator's judgment), unless otherwise excluded.

Exclusion criteria

1. Life expectancy of <3 months in the opinion of the investigator.
2. Any medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or make the participant inappropriate for the study.
3. Participants with any history of another malignancy within 3 years before the first dose of study intervention, or any evidence of residual disease from a previously diagnosed malignancy.
4. Known or suspected hypersensitivity, intolerance, or contraindication to any excipient contained in the drug formulation of sigvotatug vedotin or pembrolizumab.
5. Participants with any of the following respiratory conditions:
    1. Evidence of noninfectious or drug-induced ILD or pneumonitis
    2. Known DLCO (adjusted for hemoglobin) <50% predicted.
    3. Grade ≥3 pulmonary disease unrelated to underlying malignancy
6. Known active CNS lesions are excluded. Participants with definitively treated brain metastases (surgery and/or radiotherapy) may be eligible.
7. Major surgery (defined as a surgery requiring inpatient hospitalization of at least 48 hours) within 21 days or minor surgery within 7 days prior to first dose of study intervention.
8. Receipt of a live vaccine within 30 days prior to first dose of study intervention.
9. Pre-existing peripheral neuropathy Grade ≥2 per NCI CTCAE v5.0.
10. Uncontrolled diabetes mellitus, defined as HbA1c ≥8.0% or HbA1c between 7.0% and 8.0% with associated diabetes symptoms (polyuria or polydipsia) that are not otherwise explained.
11. Prior immune-related AE that led to anti-PD-(L)1 treatment discontinuation, required a high-dose steroid taper (≥0.5 mg/kg prednisone or equivalent per day) for >2 weeks, or required treatment with systemic immunosuppressive therapy.
12. History of autoimmune disease that has required systemic treatment in the past 2 years
13. Participants with prior solid organ or bone marrow transplantation.
14. Currently receiving a high-dose steroid (>10 mg prednisone or equivalent per day) or other immune suppressant or has a condition requiring a chronic high-dose steroid or immune suppressant.
15. Prior and concomitant therapy:
    1. Any prior treatment with MMAE-derived drugs or IB6 targeting agents.
    2. Prior systemic therapy, including anti-PD-(L)1 therapy, for locally advanced, unresectable, or metastatic NSCLC.

3. Prior radiotherapy to the lung within 6 months of first dose of study intervention, referencing the last date radiotherapy was received.
4. Chemotherapy, biologics, and/or other antitumor treatment with immunotherapy not specifically prohibited that is completed less than 4 weeks prior to first dose of study intervention, or 2 weeks for palliative radiotherapy.
5. Any prior therapy with an immune-oncology agent directed to a stimulatory or co-inhibitory T-cell receptor

16. History of or current ongoing infection, including participants positive for active HIV, HBV, or HCV.
17. Severe uncontrolled cardiac or cerebrovascular condition within the previous 6 months

Trial design

Primary purpose

Treatment

Allocation

Randomized

Interventional model

Parallel Assignment

Masking

Single Blind

714 participants in 2 patient groups

Sigvotatug Vedotin with Pembrolizumab

Experimental group

Description:
Participants will receive Sigvotatug Vedotin, administered as an IV infusion and pembrolizumab, administered as an IV infusion.

Treatment:
Drug: Sigvotatug Vedotin
Drug: Pembrolizumab

Pembrolizumab Monotherapy

Active comparator group

Description:
Participants will receive pembrolizumab, administered as an IV infusion.

Treatment:
Drug: Pembrolizumab

All locations

Hope and Healing Cancer Services | Hinsdale, IL
Veeva-enabled site

950 North York Road, Hinsdale, Illinois 60521

Not yet enrolling

BRCR Medical Center | Plantation, FL
Veeva-enabled site

8200 W Sunrise Boulevard Suite D1 -D2, Plantation, Florida 33322

Not yet enrolling

Highland Medical P.C. | Hematology Oncology Associates of Rockland
Veeva-enabled site

255 Fifth Avenue, Nyack, New York 10960

Not yet enrolling

Hope and Healing Cancer Services

New Lenox, Illinois, United States, 60451

Mid Florida Hematology and Oncology Center

Orange City, Florida, United States, 32763

Central trial contact

Pfizer CT.gov Call Center

Contact trial

Similar trials

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University of Chinese Academy Sciences

Not yet enrolling

Carcinoma, Non-Small-Cell Lung

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J Ji Yongling

Not yet enrolling

Non-Small Cell Lung Cancer

Data sourced from clinicaltrials.gov