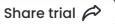




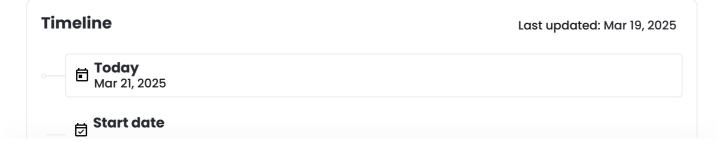
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This is a Study to Learn About How the Combination of the Study Medicines Sigvotatug Vedotin Plus Pembrolizumab Works in People With Non-small Cell Lung Cancer With High Levels of PD-L1. (Be6A Lung-02)

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	
	atug Vedotin
Study type	Funder types
Interventional 🥎	Industry ?
Identifiers	
NCT06758401	
C5751003	
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View 5 locations 🔮	
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### Sponsor of this trial

**Lead Sponsor** 



# **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.

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 HbAlc ≥8.0% or HbAlc 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**

Allocation **Primary purpose** 

Treatment Randomized

Interventional model Masking

Single Blind (?) Parallel Assignment

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**



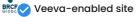
# Hope and Healing Cancer Services | Hinsdale, IL H ✓ Veeva-enabled site

950 North York Road, Hinsdale, Illinois 60521

Not yet enrolling



### **BRCR Medical Center | Plantation, FL**



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



### **H** Hope and Healing Cancer Services

New Lenox, Illinois, United States, 60451



### M Mid Florida Hematology and Oncology Center

Orange City, Florida, United States, 32763

#### **Central trial contact**

# **Pfizer CT.gov Call Center**

**Contact trial** 

### Similar trials

### Neoadjuvant Sintilimab Plus Anlotinib Therapy in IB-IIIB Resectable Non-small C...

University of Chinese Academy Sciences

Not yet enrolling (i)

Carcinoma, Non-Small-Cell Lung





Not yet enrolling (i)

Carcinoma, Non-Small-Cell Lung

# Radiation Therapy Followed by Tislelizumab and Anlotinib Aeoadjuvant/Adjuvant T...

Ji Yongling

Not yet enrolling (i)

Non-Small Cell Lung Cancer

Data sourced from clinicaltrials.gov

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