Neoadjuvant Immunotherapy in Advanced NSCLC

ClinicalTrials.gov Identifier: NCT05137912

Recruitment Status ! : Not yet recruiting
First Posted ! : November 30, 2021
Last Update Posted ! : February 7, 2022

See **Contacts and Locations**

Sponsor:
Power Life Sciences Inc.

Information provided by (Responsible Party):
Power Life Sciences Inc.

Study Description

Go to

Brief Summary:

A number of clinical trials have demonstrated the efficacy of immunotherapy prior as neoadjuvant therapy. This study evaluates whether said neoadjuvant immunotherapy may improve improve progression free survival in NSCLC. One such example would be to evaluate either single agent or an immunotherapy combination with chemotherapy. Following this, analysis of biomarkers will be conducted to provide personalization in one's regimen.

Condition or disease !	Intervention/treatment !
Lung Cancer, Non-small Cell	Biological: Immunotherapy

Detailed Description:

A number of clinical trials have demonstrated the efficacy of immunotherapy prior as neoadjuvant therapy. This study evaluates whether said neoadjuvant immunotherapy may improve improve progression free survival in NSCLC. [The Power Life Sciences Investigative Team](https://www.withpower.com) is running a study to evaluate either single agent or an immunotherapy combination with chemotherapy. Patients can contact a site administrator via the information below, or enroll directly via https://www.withpower.com/trial/phase-4-2019-e67c1. Following this, analysis of biomarkers will be conducted to provide personalization in one's regimen.

Study Design

Go to

Study Type ! :	Observational
Estimated Enrollment ! :	10 participants
Observational Model:	Other
Time Perspective:	Prospective
Official Title:	Neoadjuvant Immunotherapy in Advanced NSCLC
Estimated Study Start Date ! :	February 1, 2022
Estimated Primary Completion Date ! :	September 1, 2022
Estimated Study Completion Date ! :	December 1, 2022

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Lung cancer

U.S. FDA Resources

Groups and Cohorts

Go to

Intervention Details:

- Biological: Immunotherapy

  Patients within this intervention group will be histologically confirmed to have resectable non small cell lung cancer with stage II-IIIA.

  Patients may receive single agent immunotherapy or immunotherapy combined with chemotherapy.

Outcome Measures

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Primary Outcome Measures ! :

1. Major Pathological Response [Time Frame: 12 Weeks]

   To evaluate the major pathological response (MPR) rate of participants

Secondary Outcome Measures ! :

1. Objective Response Rate [Time Frame: 12 Weeks]

   Objective Response Rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST)

2. MPR based on diverse PD-L1 expression [Time Frame: 12 Weeks]

   Percentage of Participants with Major Pathologic Response Rates For Programmed Death Ligand 1 (PD-L1)-Positive Versus PD-L1-Negative Participants

3. Progression Free Survival [Time Frame: 12 Weeks]

   Progression Free Survival (PFS)

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: All
Sampling Method: Probability Sample

Study Population

Stage IIA-IIIA NSCLC

Criteria

Inclusion Criteria:

- >= 18 Years of Age
- Informed consent is provided
- Histologically confirmed resectable non-small cell lung cancer with stage II-IIIA (TNM 8th edition)
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- Epidermal growth factor receptor (EGFR) mutation negative and anaplastic lymphoma kinase (ALK) translocation negative Exclusion Criteria:
- EGFR mutation positive and ALK translocation positive
- Active central nervous system (CNS) metastases
- Autoimmune diseases
- Inhaled or topical steroids, and adrenal replacement steroid doses > 10 mg daily prednisone equivalent, are permitted in the absence of active autoimmune disease
- Patients with interstitial lung disease will not be included if they have symptomatic interstitial lung disease (ILD) - Grade 3-4
- Women who are breast feeding or pregnant
- Sexually active women or men of childbearing potential who are not willing to use an effective contraceptive method during the study

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT05137912***

Contacts

Contact: Michael B Gill (415) 900-4227 bask@withpower.com

Contact: Patient Support hello@withpower.com

Locations

United States, California

Power Life Sciences
San Francisco, California, United States, 94107
Contact: Michael B Gill 415-900-4227 https://www.withpower.com/contact-us@withp

Sponsors and Collaborators

Power Life Sciences Inc.

Investigators

Study Director: Michael B Gill [Power Life Sciences Inc.](www.withpower.com)

Study Documents (Full-Text)

Documents provided by Power Life Sciences Inc.:

Informed Consent Form [PDF] November 7, 2021

More Information

Go to

Additional Information:

Participating Patient Terms of Service EXIT

Immunotherapy As Neoadjuvant Therapy For Non Small Cell Lung Cancer EXIT Patient Support Line EXIT

Publications:

Jiang L, Huang J, Jiang S, Rong W, Shen Y, Li C, Tian Y, Ning J, Chen X, Yang Y, Ding Z, Li Z, Luo Q. The surgical perspective in neoadjuvant immunotherapy for resectable non-small cell lung cancer. Cancer Immunol Immunother. 2021 Aug;70(8):2313-2321. doi: 10.1007/s00262021-02847-1. Epub 2021 Jan 29.

Broderick SR. Adjuvant and Neoadjuvant Immunotherapy in Non-small Cell Lung Cancer. Thorac Surg Clin. 2020 May;30(2):215-220. doi: 10.1016/j.thorsurg.2020.01.001.

Gutierrez-Sainz L, Cruz-Castellanos P, Higuera O, de Castro-Carpeno J. Neoadjuvant Chemoimmunotherapy in Patients with Resectable Non-small Cell Lung Cancer. Curr Treat Options Oncol. 2021 Aug 23;22(10):91. doi: 10.1007/s11864-021-00885-6.

Responsible Party: Power Life Sciences Inc.
ClinicalTrials.gov Identifier: NCT05137912 History of Changes
Other Study ID Numbers: e4c2e8edac362acab7123654b9e734
First Posted: November 30, 2021 Key Record Dates
Last Update Posted: February 7, 2022
Last Verified: January 2022
Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided
Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:

Carcinoma, Non-Small-Cell Lung	Thoracic Neoplasms
Carcinoma, Bronchogenic	Neoplasms by Site
Bronchial Neoplasms	Neoplasms
Lung Neoplasms	Lung Diseases
Respiratory Tract Neoplasms	Respiratory Tract Diseases