A Study of Atezolizumab as Neoadjuvant and Adjuvant Therapy in Resectable Non-Small Cell Lung Cancer (NSCLC) - Lung Cancer Mutation Consortium (LCMC3)

ClinicalTrials.gov Identifier: NCT02927301

Recruitment Status ! : Active, not recruiting
First Posted ! : October 7, 2016
Results First Posted ! : May 17, 2021
Last Update Posted ! : December 22, 2022

View this study on Beta.ClinicalTrials.gov

Sponsor:

Genentech, Inc.

Information provided by (Responsible Party):

Genentech, Inc.

Study Details | Tabular View | Study Results | Disclaimer

How to Read a Study Record

Study Description

Go to

Brief Summary:

This study was designed to evaluate the safety and efficacy of neoadjuvant and adjuvant atezolizumab in participants with resectable Non-Small Cell Lung Cancer (NSCLC). Neoadjuvant therapy consisted of two 21-day cycles with atezolizumab. Following surgery, adjuvant therapy consisted of up to 12 months of atezolizumab in participants who demonstrate clinical benefit with neoadjuvant therapy. All participants who undergo surgery entered a surveillance period, which consisted of standardized blood sample collection and Chest CT Scans, for up to 2 years. All participants were monitored for disease recurrence and survival for up to 3 years after last dose of study drug.

Condition or disease !	Intervention/treatment !	Phase !
Non-Small Cell Lung Cancer	Drug: Atezolizumab (MPDL3280A), an engineered anti-PD-L1 antibody	Phase 2

Study Design

Go to

Study Type ! :	Interventional (Clinical Trial)
Actual Enrollment ! :	181 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment

Official Title:	A Phase II, Open-Label, Multicenter, Single-Arm Study to Investigate the Efficacy and Safety of Atezolizumab as Neoadjuvant and Adjuvant Therapy in Patients With Stage IB, II, IIIA, or Selected IIIB Resectable and Untreated Non-Small Cell Lung Cancer
Actual Study Start Date ! :	April 20, 2017
Actual Primary Completion Date ! :	May 7, 2020
Estimated Study Completion Date ! :	May 3, 2024

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Lung cancer

MedlinePlus related topics: Lung Cancer

Drug Information available for: Atezolizumab

U.S. FDA Resources

Arms and Interventions

Go to

Arm !	Intervention/treatment !
Experimental: Atezolizumab Participants received two cycles of atezolizumab as neoadjuvant therapy prior to surgery. Participants who demonstrated clinical benefit were eligible to receive up to 12 months of atezolizumab.	Drug: Atezolizumab (MPDL3280A), an engineered anti-PD-L1 antibody Atezolizumab was given as 1200 milligrams (mg) via intravenous (IV) infusion on Day 1 of each 21-day cycle. Other Name: RO5541267, MPDL3280A

Outcome Measures

Go to

Primary Outcome Measures ! :

1. Percentage of Participants With Major Pathologic Response (MPR) [Time Frame: After surgery (approximately 10 weeks)]

   Major pathologic response (defined as ≤ 10% of viable tumor cells), scored by a pathologist, based on surgical resection as defined by prior studies.

Secondary Outcome Measures ! :

1. Objective Response Rate (ORR) Per Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1 [Time Frame: After surgery (approximately 10 weeks)]

   Objective response rate is the proportion of participants who are objective responders (Complete Response and Partial Response are considered as responders, Stable Disease, Progressive Disease and Not Evaluable are considered as nonresponders) in the PD-L1 positive (TC123IC123) and negative (TC0IC0) groups.

2. Percentage of Participants With Major Pathologic Response Rates For Programmed Death Ligand 1 (PD-L1)-Positive Versus PD-L1-Negative Participants [Time Frame: After surgery (approximately 10 weeks)]

   Major pathologic response (defined as ≤ 10% of viable tumor cells), scored by a pathologist, based on surgical resection as defined by prior studies.

3. Percentage of Participants With Adverse Events [Time Frame: From Baseline until 90 days after end of treatment (approximately 16.5 months overall)]

Eligibility Criteria

Go to

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
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Pathologically documented Stage IB, II, IIIA, or selected IIIB, including T3N2 or T4 (by size criteria, not by mediastinal invasion) NSCLC
- Adequate pulmonary and cardiac function
- Available biopsy of primary tumor with adequate samples
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 Exclusion

Criteria:

- NSCLC that is clinically T4 by virtue of mediastinal organ invasion or Stage IIIB by virtue of N3 disease
- Any prior therapy for lung cancer within 3 years.
- Prior treatment with anti-PD-1 or PD-L1 therapies
- History or risk of autoimmune disease

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): ***NCT02927301***

Locations

Show 21 study locations

Sponsors and Collaborators

Genentech, Inc.

Investigators

Study Director: Clinical Trials Hoffmann-La Roche

Study Documents (Full-Text)

Documents provided by Genentech, Inc.:

Study Protocol [PDF] February 11, 2021

Statistical Analysis Plan [PDF] June 16, 2020

More Information

Go to

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Chaft JE, Oezkan F, Kris MG, Bunn PA, Wistuba II, Kwiatkowski DJ, Owen DH, Tang Y, Johnson BE, Lee JM, Lozanski G, Pietrzak M, Seweryn M, Byun WY, Schulze K, Nicholas A, Johnson A, Grindheim J, Hilz S, Shames DS, Rivard C, Toloza E, Haura EB, McNamee CJ, Patterson GA, Waqar SN, Rusch VW, Carbone DP; LCMC study investigators. Neoadjuvant atezolizumab for resectable non-small cell lung cancer: an open-label, single-arm phase II trial. Nat Med. 2022 Oct;28(10):2155-2161. doi: 10.1038/s41591-022-01962-5. Epub 2022 Sep 12.

Responsible Party:	Genentech, Inc.
ClinicalTrials.gov Identifier:	NCT02927301 History of Changes
Other Study ID Numbers:	ML39236
First Posted:	October 7, 2016 Key Record Dates
Results First Posted:	May 17, 2021
Last Update Posted:	December 22, 2022
Last Verified:	December 2022

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Lung Neoplasms	Carcinoma, Bronchogenic
Carcinoma, Non-Small-Cell Lung	Bronchial Neoplasms
Respiratory Tract Neoplasms	Atezolizumab
Thoracic Neoplasms	Antibodies
Neoplasms by Site	Antibodies, Monoclonal
Neoplasms	Immunologic Factors
Lung Diseases	Physiological Effects of Drugs
Respiratory Tract Diseases	Antineoplastic Agents