A Study of Neoadjuvant Chemotherapy Plus Nivolumab Versus Neoadjuvant Chemotherapy Plus Placebo, Followed by Surgical Removal and Adjuvant Treatment With Nivolumab or Placebo for Participants With Surgically Removable Early Stage Non-small Cell Lung Cancer

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT04025879	RECRUITING	JULY 19, 2019	NOVEMBER 23, 2021

STUDY DESCRIPTION

Brief Summary

The main purpose of the study is to examine if periadjuvant (neoadjuvant, then adjuvant) immunotherapy will prolong event free survival in participants with early stage non-small cell lung cancer.

Condition or Disease: Carcinoma, Non-Small-Cell Lung

Intervention/treatment: Biological: Nivolumab
Drug: Carboplatin
Drug: Cisplatin
Drug: Paclitaxel
Drug: Pemetrexed
Drug: Placebo
Drug: Docetaxel

Phase: Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 452 participants

Intervention Model : Parallel Assignment

Masking: Double (Participant, Investigator)

Primary Purpose: Treatment

Official Title: A Phase 3, Randomized, Double-blind Study of Neoadjuvant Chemotherapy Plus Nivolumab Versus Neoadjuvant Chemotherapy Plus Placebo, Followed by Surgical Resection and Adjuvant Treatment With Nivolumab or Placebo for Participants With Resectable Stage II-IIIB Non-small Cell Lung Cancer

Actual Study Start Date: November 2019

Estimated Primary Completion Date: December 2023

Estimated Study Completion Date: September 2024

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Neoadj. Nivo+ Pt-based Doublet Chemo followed by Adj. Nivo	Biological: Nivolumab Specified dose on specified days Drug: Carboplatin Specified dose on specified days Drug: Cisplatin Specified dose on specified days Drug: Paclitaxel Specified dose on specified days Drug: Pemetrexed Specified dose on specified days Drug: Docetaxel Specified dose on specified days

Placebo Comparator: Neoadj. Plac. + Pt-based Doublet Chemo followed by Adj.Plac.	Drug: Carboplatin Specified dose on specified days Drug: Cisplatin Specified dose on specified days Drug: Paclitaxel Specified dose on specified days Drug: Pemetrexed Specified dose on specified days Drug: Placebo Specified dose on specified days Drug: Docetaxel Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures: 1. Event-Free Survival (EFS) as Assessed by Blinded Independent Central Review (BICR) [Time Frame: 5 Years from randomization]

Secondary Outcome Measures:
1. Overall Survival (OS) [Time Frame: Up to 5 years from randomization]
2. Pathologic Complete Response (pCR) Rate as Assessed by Blinded Independent Pathology Review (BIPR) [Time Frame: At the time of surgery, between week 12 to week 18]
3. Major Pathological Response (MPR) Rate as Assessed by Blinded Independent Pathology Review [Time Frame: Up to 8 weeks following completion of neoadjuvant surgery, approximately study week 22]
4. Incidence of Serious Adverse Events (SAEs) [Time Frame: Up to 80 weeks]
5. Incidence of Adverse Events (AEs) [Time Frame: Up to 80 weeks]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

For more information regarding Bristol-Myers Squibb Clinical Trial participation, please visit www.BMSStudyConnect.com
Inclusion Criteria:
Participants with suspected or histologically confirmed Stage IIA (> 4 cm) to IIIB (T3N2) non-small cell lung carcinoma (NSCLC) with disease that is considered resectable No brain metastasis Treatment-naive for NSCLC (no prior systemic anti-cancer treatment) Ability to provide surgical or biopsy tumor tissue for biomarkers Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤ 1
Exclusion Criteria:
Participants with an active, known or suspected autoimmune disease Any positive test for hepatitis B virus or hepatitis C virus or human immunodeficiency virus (HIV) Any previous anti-cancer treatment including cytotoxic, IO treatment, targeted agents, or radiotherapy for NSCLC Prior treatment with any anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways
Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email: Clinical.Trials@bms.com
Contact: First line of the email MUST contain NCT# and Site #.

Locations

United States, California	Local Institution	Fresno
United States, Florida	H. Lee Moffitt Cancer Center	Tampa
United States, Georgia	Northside Hospital	Atlanta
United States, Georgia	Augusta University	Augusta
United States, Illinois	Northwestern University	Chicago
United States, Illinois	University Of Illinois At Chicago	Chicago
United States, Illinois	University of Chicago Medical Center	Orland Park
United States, Kansas	Local Institution	Westwood
United States, Maryland	Rcca Md Llc	Bethesda
United States, Massachusetts	Dana Farber Cancer Institute	Boston
United States, Massachusetts	Massachusetts General Hospital	Boston
United States, Michigan	Munson Medical Center	Traverse City
United States, New Hampshire	Dartmouth-Hitchcock Medical Center	Lebanon

United States, Ohio	Good Samaritan Hospital	Cincinnati
United States, Ohio	Local Institution	Cincinnati
United States, Ohio	University Hospitals Cleveland Medical Center	Cleveland
United States, Pennsylvania	Local Institution	Philadelphia
United States, Texas	The University of Texas MD Anderson Cancer Center-merge	Houston
United States, Virginia	Hematology-Oncology Associates Of Fredricksburg, Inc	Fredericksburg
Argentina, Buenos Aires	Local Institution	Ciudad Autonoma Beunos Aires
Argentina, Buenos Aires	Hospital Britanico De Buenos Aires	Ciudad Autónoma de Buenos Aires
Argentina	Hospital Italiano De Buenos Aires	Caba
Argentina	Instituto Medico Especialazado Alexander Fleming	Caba
Australia, New South Wales	Chris O'Brien Lifehouse Hospital	Sydney
Australia, Queensland	Local Institution	Greenslopes
Australia, Victoria	Austin Hospital	Heidelberg
Australia, Victoria	St Vincent's Hospital	Melbourne
Australia, Victoria	Ballarat Base Hospital	North Ballarat
Belgium	Local Institution	Edegem
Belgium	Local Institution	Liege
Belgium	Local Institution	Roeselare
Brazil, Ceara	Local Institution	Fortaleza
Brazil, Minas Gerais	PERSONAL Oncologia de Precisao e Personalizada	Belo Horizonte
Brazil, RIO Grande DO SUL	ONCOSITE - Centro de Pesquisa Clinica em Oncologia	Ijui
Brazil, SAO Paulo	Real E Benemerita Associacao Portuguesa De Beneficencia	São Paulo
Brazil	Fundacao Antonio Prudente-Hospital Ac Camargo	Sao Paulo
Brazil	Hospital Israelita Albert Einstein	Sao Paulo
Canada, Ontario	Local Institution	Oshawa
Canada, Ontario	Local Institution	Windsor
Canada, Quebec	Local Institution	Greenfield Park
Canada, Quebec	Local Institution	Montreal
Canada, Quebec	Local Institution	Montreal
Canada, Quebec	Local Institution	Montreal
China, Beijing	Local Institution	Beijing
China, BEI	Local Institution	Beijing
China, Fujian	Local Institution	Fuzhou
China, Fujian	Local Institution	Fuzhou
China, Hubei	Local Institution	Hubei Sheng
China, Hunan	Local Institution	Changsha
China, Hunan	Local Institution	Changsha
China, Hunan	Local Institution	Changsha
China, Jilin	Local Institution	Changchun
China, Shanghai	Local Institution	Shanghai
China, Shanghai	Local Institution	Shanghai
China, Sichuan	Local Institution	Chengdu
China, Zhejiang	Local Institution	Hangzhou
China	Local Institution	Shanghai
Czechia	Onkologicka klinika VFN a 1. LF UK	Praha 2

Czechia	Pneumologicka klinika 1. LF a TN	Praha 4
France	Chu Jean Minjoz	Besancon
France	Local Institution	La Tronche
France	Local Institution	Montpellier
France	Local Institution	Paris Cedex 18
France	Local Institution	Paris Cedex 20
France	Local Institution	Rennes Cedex 9
France	Local Institution	Rouen
Germany	Campus Virchow Klinikum Der Charite	Berlin
Germany	Krankenhaus Nordwest GmbH	Frankfurt
Germany	MVZ II der Niels Stensen Kliniken	Georgsmarienhuette
Germany	Evangelisches Krankenhaus Hamm	Hamm
Germany	Thoraxklinik-Heidelberg gGmbH	Heidelberg
Germany	Klinikverbund Allgaeu gGmbH	Immenstadt
Germany	Kliniken Der Stadt Koeln Ggmbh Krankenhaus Mehrheim	Koeln
Germany	Klinik Löwenstein gGmbH	Loewenstein
Germany	Klinikum Ludwigsburg	Ludwigsburg
Germany	Universitaetsklinikum Schleswig-Holstein	Luebeck
Germany	Krankenhaus Bethanien Moers	Moers
Germany	Klinikum rechts der Isar der TU	Muenchen
Ireland, Dublin	Local Institution	Dublin 7
Ireland	Local Institution	Dublin
Italy	IRST Meldola	Forlì
Italy	Fondazione IRCCS Ca Granda Ospedale Maggiore Policlinico	Milano
Italy	Local Institution	Parma
Japan, Aichi	Local Institution	Nagoya-shi
Japan, Chiba	Local Institution	Kashiwa-shi
Japan, Fukuoka	Local Institution	Kitakyushu-shi
Japan, Fukushima	Local Institution	Fukushima-shi
Japan, Hyogo	Local Institution	Kobe-shi
Japan, Ishikawa	Local Institution	Kanazawa-shi
Japan, Kanagawa	Local Institution	Yokohama
Japan, Miyagi	Local Institution	Sendai-shi
Japan, Osaka	Local Institution	Sakai-shi
Japan, Saitama	Local Institution	Kitaadachigun
Japan, Tokyo	Local Institution	Bunkyo-ku
Japan, Tokyo	Local Institution	Bunkyo-ku
Japan, Tokyo	Local Institution	Chuo-ku
Japan, Tokyo	Local Institution	Chuo-ku
Japan	Local Institution	Hiroshima
Mexico, Jalisco	Hospital Civil De Guadalajara Juan I Menchaca	Guadalajara
Mexico, Nuevo Leon	Hospital Universitario Doctor Jose Eleuterio Gonzalez	Monterrey
Mexico	Centro Estatal de Cancerologia	Chihuahua
Netherlands	Local Institution	Groningen
Netherlands	Local Institution	Rotterdam

Poland	Oddzial Kliniczny Chirurgii Klatki Piersiowej	Krakow
Puerto Rico	Puerto Rico Medical Research Center	Hato Rey
Puerto Rico	Local Institution	San Juan
Romania	Local Institution	Bucuresti
Romania	Local Institution	Cluj-Napoca
Romania	Local Institution	Floresti
Russian Federation	Local Institution	Krasnodar
Russian Federation	Local Institution	Moscow
Russian Federation	Local Institution	Saint-Petersburg
Russian Federation	Local Institution	St. Petersburg
Russian Federation	Local Institution	St. Petersburg
Spain	Local Institution	Barcelona
Spain	Local Institution	L'Hospitalet
Spain	Local Institution	Madrid
Spain	Local Institution	Majadahonda - Madrid
Spain	Local Institution	Valencia
Taiwan	Local Institution	Kaohsiung City
Taiwan	Local Institution	Kaohsiung
Taiwan	Local Institution	New Taipei City
Taiwan	Local Institution	Taipei City
United Kingdom, Suffolk	Local Institution	Ipswich
United Kingdom	Local Institution	Exeter
United Kingdom	Local Institution	Guildford
United Kingdom	Local Institution	Taunton

Sponsors and Collaborators

Bristol-Myers Squibb

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

Responsible Party :	Bristol-Myers Squibb
ClinicalTrials.gov Identifier :	NCT04025879
Other Study ID Numbers :	CA209-77T, 2019-000262-38
First Posted :	July 19, 2019
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Last Verified :	November 2021
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Additional relevant MeSH terms :	*Carcinoma, Non-Small-Cell Lung* *Carcinoma, Bronchogenic* *Bronchial Neoplasms* *Lung Neoplasms* *Respiratory Tract Neoplasms* *Thoracic Neoplasms* *Neoplasms by Site* *Neoplasms* *Lung Diseases* *Respiratory Tract Diseases*