



# An Investigational Immuno-therapy Trial of Nivolumab, or Nivolumab Plus Ipilimumab, or Nivolumab Plus Platinum-doublet Chemotherapy, Compared to Platinum Doublet Chemotherapy in Patients With Stage IV Non-Small Cell Lung Cancer (NSCLC)

**CLINICALTRIALS.GOV IDENTIFIER**  
NCT02477826

**RECRUITMENT STATUS**  
RECRUITING

**FIRST POSTED**  
JUNE 23, 2015

**LAST UPDATE POSTED**  
SEPTEMBER 21, 2021

## STUDY DESCRIPTION

### Brief Summary

The purpose of this study is to show that Nivolumab, or Nivolumab plus Ipilimumab, or Nivolumab plus Platinum-Doublet Chemotherapy improves progression free survival and/or overall survival compared with chemotherapy in patients with advanced lung cancer.

**Condition or Disease:** Non-Small Cell Lung Cancer

**Intervention/treatment:** Drug: Nivolumab  
Drug: Ipilimumab  
Drug: Carboplatin  
Drug: Cisplatin  
Drug: Gemcitabine  
Drug: Pemetrexed  
Drug: Paclitaxel

**Phase:** Phase 3

## DETAILED DESCRIPTION

N/A

## STUDY DESIGN

<b>Study Type:</b>	Interventional	<b>Actual Study Start Date:</b>	August 2015
<b>Estimated Enrollment :</b>	1980 participants	<b>Estimated Primary Completion Date:</b>	August 2024
<b>Intervention Model :</b>	Parallel Assignment	<b>Estimated Study Completion Date:</b>	August 2024
<b>Masking:</b>	None (Open Label) ()		
<b>Primary Purpose:</b>	Treatment		
<b>Official Title:</b>	An Open-Label, Randomized Phase 3 Trial of Nivolumab, or Nivolumab Plus Ipilimumab, or Nivolumab Plus Platinum Doublet Chemotherapy Versus Platinum Doublet Chemotherapy in Subjects With Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC)		

## ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Arm A: Nivolumab Nivolumab intravenously (IV) as specified	Drug: Nivolumab
Experimental: Arm B: Nivolumab + Ipilimumab Nivolumab + Ipilimumab IV as specified	Drug: Nivolumab Drug: Ipilimumab
Experimental: Arm C: Nivolumab + Platinum doublet chemotherapy Nivolumab + Platinum doublet chemotherapy (IV) dose as specified	Drug: Nivolumab Drug: Carboplatin Drug: Cisplatin Drug: Gemcitabine Drug: Pemetrexed Drug: Paclitaxel

Experimental: Arm D: Platinum doublet chemotherapy  
Chemotherapy administered on specified days of IV chemotherapy

Drug: Carboplatin

Drug: Cisplatin

Drug: Gemcitabine

Drug: Pemetrexed

Drug: Paclitaxel

## OUTCOME MEASURES

Primary Outcome Measures: 1. Overall survival (OS) [ Time Frame: approximately 48 months ]

2. Progression-free Survival (PFS) as determined by blinded independent central review (BICR) [ Time Frame: approximately 40 months ]

Secondary Outcome Measures:

1. Objective response rate (ORR) [ Time Frame: Up to 48 months ]

ORR of nivolumab monotherapy and nivolumab in combination with ipilimumab to platinum-doublet chemotherapy in subjects with advanced lung cancer

2. Disease related symptom improvement as measured by the Lung Cancer Symptom Score (LCSS) in all subjects [ Time Frame: Up to 48 months ]

Disease related symptom improvement assessed at each dosing for 6 months, then every 6 weeks while on treatment

## 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 BMS clinical trial participation, please visit [www.BMSStudyConnect.com](http://www.BMSStudyConnect.com)

Inclusion Criteria:

Subjects with histologically confirmed Stage IV or recurrent NSCLC squamous or non-squamous histology, with no prior systemic anticancer therapy Subjects must have programmed death-ligand 1 (PD -L1) immunohistochemical (IHC) testing, with results, performed by the central lab during the Screening period Eastern Cooperative Oncology Group (ECOG) Performance Status of  $\leq 1$  Measurable disease by CT or MRI per response evaluation criteria in solid tumors version 1.1 (RECIST 1.1) criteria

Exclusion Criteria:

Subjects with untreated Central nervous system (CNS) metastases are excluded Subjects with an active, known or suspected autoimmune disease are excluded Any positive test for hepatitis B virus or hepatitis C virus or human immunodeficiency virus (HIV) indicating acute or chronic infection Other protocol defined inclusion/exclusion criteria could 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](mailto:Clinical.Trials@bms.com)

Contact: First line of the email MUST contain NCT# and Site #.

### Locations

United States, Alabama	Southern Cancer Center, Inc.	Mobile
United States, California	Local Institution	La Jolla
United States, California	California Pacific Medical Center	San Francisco
United States, Connecticut	Yale University	New Haven
United States, Georgia	Emory University Hospital	Atlanta
United States, Georgia	Northwest Georgia Oncology Centers, P.C.	Marietta
United States, Kentucky	Baptist Health Lexington	Lexington
United States, Maryland	Sidney Kimmel Comprehensive Cancer Center At Johns Hopkins	Baltimore
United States, Massachusetts	Local Institution	Boston
United States, Massachusetts	Local Institution	Boston
United States, Michigan	Local Institution	Southfield
United States, Minnesota	Local Institution	Rochester
United States, Missouri	Washington University School Of Medicine	Saint Louis
United States, New York	Roswell Park Cancer Institute	Buffalo
United States, New York	Memorial Sloan Kettering Nassau	New York

United States, North Carolina	Duke University Medical Center	Durham
United States, Ohio	University Hospitals	Cleveland
United States, Ohio	The Ohio State University	Columbus
United States, Pennsylvania	Lehigh Valley Health Network	Allentown
United States, Pennsylvania	St. Mary Medical Center	Langhorne
United States, Pennsylvania	Fox Chase Cancer Center	Philadelphia
United States, Pennsylvania	Thomas Jefferson University	Philadelphia
United States, Pennsylvania	Guthrie Medical Group, Pc	Sayre
United States, South Carolina	Hollings Cancer Center	Charleston
United States, South Carolina	Greenville Health System	Greenville
United States, South Carolina	St Francis Hospital	Greenville
United States, Tennessee	Vanderbilt University Medical Center	Nashville
United States, Texas	The University Of Texas	Dallas
United States, Texas	University Of Texas Southwestern Medical Center	Dallas
United States, Texas	University Of Texas Md Anderson Cancer Ctr	Houston
United States, Utah	Huntsman Cancer Institute At The Univ. Of Utah	Salt Lake City
United States, Washington	Kadlec Clinical Hematology and Oncology	Kennewick
Argentina, Buenos Aires	COIBA	Berazategui
Argentina, Buenos Aires	Instituto Alexander Fleming	Capital Federal
Argentina, Buenos Aires	Hospital Italiano De Buenos Aires	Ciudad Autonoma De Buenos Aire
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Argentina, Cordoba	Hospital Privado Centro Medico De Cordoba	Córdoba
Argentina, RIO Negro	Clinica Viedma S.A.	Viedma
Argentina, Tucuman	Centro Medico San Roque	San Miguel de Tucuman
Argentina	Local Institution	Caba
Argentina	Instituto Oncologico De Cordoba	Cordoba
Argentina	Clinica Privada Universitaria Reina Fabiola	Cordoba
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Australia, New South Wales	Blacktown Hospital	Blacktown
Australia, New South Wales	Local Institution	Gosford
Australia, New South Wales	Tamworth Hospital	Tamworth
Australia, Queensland	Princess Alexandra Hospital	Brisbane
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Australia, Victoria	Local Institution	Clayton
Australia, Victoria	St Vincent's Hospital	Fitzroy
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Belgium	Local Institution	Hasselt

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Brazil	Local Institution	Rio De Janeiro
Brazil	Local Institution	Sao Paulo
Brazil	Local Institution	Sao Paulo
Brazil	Local Institution	Sao Paulo
Canada, Alberta	Cross Cancer Institute	Edmonton
Canada, Newfoundland and Labrador	Dr. H.Bliss Murphy Cancer Centre	St. John's
Canada, Ontario	London Regional Cancer Program	London
Canada, Quebec	Jewish General Hospital	Montreal
Canada, Quebec	CISSS du Bas-Saint-Laurent Hopital Regional de Rimouski	Rimouski
Canada, Quebec	Centre integre universitaire de sante et de service sociaux de l'estrie - CHUS	Sherbrooke
Canada, Quebec	Centre integre universitaire de sante et de services sociaux de la Mauricie-et-du-Centre-du-Quebec	Trois-Rivieres
Canada	Institut Universitaire de Cardiologie et de Pneumologie de Quebec - Universite Laval	Quebec
Canada	CHU de Quebec - Universite Laval	Quebec
Chile, Metropolitana	Fundacion Arturo Lopez Perez	Santiago
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Chile, Valparaiso	Instituto Oncologico	Vina Del Mar
China, Anhui	Local Institution	Hefei
China, Beijing	Local Institution	Beijing
China, Beijing	Local Institution	Beijing
China, Beijing	Local Institution	Beijing
China, Chongqing	Local Institution	Chongqing
China, Guangdong	Local Institution	Guangzhou
China, Guangdong	Local Institution	Guangzhou
China, Guangdong	Local Institution	Guangzhou
China, Hainan	Local Institution	Haikou
China, Heilongjiang	Local Institution	Haerbin
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China, Henan	Local Institution	Zhengzhou
China, Hunan	Local Institution	Changsha
China, Hunan	Local Institution	Changsha
China, Jiangsu	Local Institution	Nanjing
China, Jiangxi	Local Institution	Nanchang
China, Jilin	Local Institution	Changchun
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China, Shan3xi	Local Institution	Xi'an
China, Shandong	Local Institution	Qingdao

China, Shanghai	Local Institution	Shanghai
China, Shanghai	Local Institution	Shanghai
China, Shanghai	Local Institution	Shanghai
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China, Zhejiang	Local Institution	Hangzhou
China, Zhejiang	Local Institution	Hangzhou
China	Local Institution	Beijing
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China	Local Institution	Chongqing
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China	Local Institution	Hangzhou
China	Local Institution	Hangzhou
China	Local Institution	Kunming
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Colombia, Risaralda	Oncologos Del Occidente Sa	Pereira
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Colombia	Hospital Universitario San Ignacio	Bogota
Colombia	Hospital Pablo Tobon Uribe	Medellin
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Czechia	Klinika plicnich nemoci a tuberkulozy	Olomouc
Czechia	Pneumologicka klinika 1. LF a TN	Praha 4
Czechia	Oddeleni Onkologie	Pribram
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France	Local Institution	Bron Cedex
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France	Local Institution	Limoges cedex
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Italy	Ospedale S.Maria	Terni
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Japan, Tokyo	Local Institution	Chuo-ku
Japan, Tokyo	Local Institution	Koto-ku
Japan, Tokyo	Local Institution	Shinjuku-ku
Japan, Wakayama	Local Institution	Wakayama-shi
Japan, Yamaguchi	Local Institution	Ube-shi
Korea, Republic of, Chungcheonbuk-do	Local Institution	Cheongju-si
Korea, Republic of, Gyeonggi-do	Local Institution	Seongnam-si
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Seoul
Lebanon	Local Institution	Beirut
Lebanon	Local Institution	Beirut
Mexico, Distrito Federal	Local Institution	Df
Mexico, Distrito Federal	Local Institution	Mexico
Mexico, Estado DE Mexico	Phylasis Clinicas Research S de R. L. de C. V.	Cuautitlan
Mexico, Estado DE Mexico	Local Institution	Toluca
Mexico, Jalisco	Instituto Jalisciense De Cancerologia	Guadalajara
Mexico, Michoacan	Local Institution	Morelia
Mexico, Nuevo LEON	Axis Heilsa S de RI de Cv	Monterrey
Mexico, Yucatan	Medical Care & Research	Merida
Mexico	Local Institution	Chihuahua

Mexico	Centro de Alta Especialidad en Reumatologia e Investigacion del Potosi S.C.	San Luis Potosi
Mexico	Local Institution	San Luis Potosi
Netherlands	Local Institution	Amsterdam
Netherlands	Local Institution	Amsterdam
Netherlands	Local Institution	Breda
Netherlands	Local Institution	Rotterdam
Netherlands	Local Institution	Veldhoven
Peru	Clinica Ricardo Palma	Lima
Peru	Instituto Nacional De Enfermedades Neoplasicas	Lima
Peru	Clinica San Felipe- Unidad de Oncologia Medica	Lima
Peru	Instituto Oncologico Miraflores	Lima
Peru	Oncocenter Peru SAC - Oncosalud	Lima
Poland	Ambulatorium Chemioterapii	Bydgoszcz
Poland	Wojewodzkie Centrum Onkologii	Gdansk
Poland	Oddzial Onkologii I Radioterapii Szpital Morski Im. Pck	Gdynia
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Romania	Institutul Clinic Fundeni	Bucharest
Romania	Sf. Nectarie Oncology Center	Craiova
Romania	S.C. Radiotherapy Center Cluj S.R.L.	Floresti
Romania	Prof. Dr. Ion Chiricuta Institute Of Oncology Day Care Dep	Romania
Russian Federation	Local Institution	Chelyabinsk
Russian Federation	Local Institution	Kazan
Russian Federation	Local Institution	Moscow
Russian Federation	Local Institution	Saint-Petersburg
Russian Federation	Local Institution	St. Petersburg
Russian Federation	Local Institution	St. Petersburg
Russian Federation	Local Institution	Ufa
Saudi Arabia	Local Institution	Riyadh 11426
Saudi Arabia	Local Institution	Riyadh-11211
South Africa, Gauteng	Local Institution	Johannesburg
South Africa, Gauteng	Local Institution	Pretoria
South Africa, Gauteng	Local Institution	Saxonwold, Johannesburg
South Africa	Local Institution	Vereeniging
Spain, Madrid	Local Institution	Majadahonda
Spain	Local Institution	Badalona (Barcelona)
Spain	Local Institution	Barcelona
Spain	Local Institution	Madrid
Spain	Local Institution	Sevilla
Spain	Local Institution	Valencia
Switzerland	Klinik Fur Onkologie	Basel
Switzerland	Kantonsspital Graubuenden	Chur
Switzerland	Centre hospitalier universitaire Vaudois (CHUV)	Lausanne



Switzerland	Local Institution	Winterthur
Taiwan	Local Institution	Taichung
Taiwan	Local Institution	Taipei
Taiwan	Local Institution	Taipei
Taiwan	Local Institution	Taipei
Taiwan	Local Institution	Tao-Yuan County
Turkey	Local Institution	Ankara
Turkey	Local Institution	Antalya
Turkey	Local Institution	Kayseri
United Arab Emirates	Local Institution	Al Ain
United Kingdom, Cleveland	Local Institution	Middlesbrough
United Kingdom, Greater London	Local Institution	London
United Kingdom, Greater London	Local Institution	London
United Kingdom, Greater London	Local Institution	London
United Kingdom, Hampshire	Local Institution	Southampton
United Kingdom, Leicestershire	Local Institution	Leicester
United Kingdom, WEST Midlands	Local Institution	Birmingham
United Kingdom	Local Institution	Cambridgeshire
United Kingdom	Local Institution	Edinburgh
United Kingdom	Local Institution	Surrey

#### Sponsors and Collaborators

Bristol-Myers Squibb

Ono Pharmaceutical Co. Ltd

#### Investigator

Study Director : Bristol-Myers Squibb Bristol-Myers Squibb

#### MORE INFORMATION

##### Other Publications

Reck M, Schenker M, Lee KH, Provencio M, Nishio M, Lesniewski-Kmak K, Sangha R, Ahmed S, Raimbourg J, Feeney K, Corre R, Franke FA, Richardet E, Penrod JR, Yuan Y, Nathan FE, Bhagavatheeswaran P, DeRosa M, Taylor F, Lawrance R, Brahmer J. Nivolumab plus ipilimumab versus chemotherapy as first-line treatment in advanced non-small-cell lung cancer with high tumour mutational burden: patient-reported outcomes results from the randomised, open-label, phase III CheckMate 227 trial. *Eur J Cancer*. 2019 Jul;116:137-147. doi: 10.1016/j.ejca.2019.05.008. Epub 2019 Jun 11.

Hellmann MD, Ciuleanu TE, Pluzanski A, Lee JS, Otterson GA, Audigier-Valette C, Minenza E, Linardou H, Burgers S, Salman P, Borghaei H, Ramalingam SS, Brahmer J, Reck M, O'Byrne KJ, Geese WJ, Green G, Chang H, Szustakowski J, Bhagavatheeswaran P, Healey D, Fu Y, Nathan F, Paz-Ares L. Nivolumab plus Ipilimumab in Lung Cancer with a High Tumor Mutational Burden. *N Engl J Med*. 2018 May 31;378(22):2093-2104. doi: 10.1056/NEJMoa1801946. Epub 2018 Apr 16.

Reck M, Ciuleanu TE, Lee JS, Schenker M, Audigier-Valette C, Zurawski B, Linardou H, Otterson GA, Salman P, Nishio M, de la Mora Jimenez E, Lesniewski-Kmak K, Albert I, Ahmed S, Syrigos K, Penrod JR, Yuan Y, Blum SI, Nathan FE, Sun X, Moreno-Koehler A, Taylor F, O'Byrne KJ. First-Line Nivolumab Plus Ipilimumab Versus Chemotherapy in Advanced NSCLC With 1% or Greater Tumor PD-L1 Expression: Patient-Reported Outcomes From CheckMate 227 Part 1. *J Thorac Oncol*. 2021 Apr;16(4):665-676. doi: 10.1016/j.jtho.2020.12.019. Epub 2021 Jan 21.

Hellmann MD, Paz-Ares L, Bernabe Caro R, Zurawski B, Kim SW, Carcereny Costa E, Park K, Alexandru A, Lupinacci L, de la Mora Jimenez E, Sakai H, Albert I, Vergnenegre A, Peters S, Syrigos K, Barlesi F, Reck M, Borghaei H, Brahmer JR, O'Byrne KJ, Geese WJ, Bhagavatheeswaran P, Rabindran SK, Kasinathan RS, Nathan FE, Ramalingam SS. Nivolumab plus Ipilimumab in Advanced Non-Small-Cell Lung Cancer. *N Engl J Med*. 2019 Nov 21;381(21):2020-2031. doi: 10.1056/NEJMoa1910231. Epub 2019 Sep 28.

##### Responsible Party :

Bristol-Myers Squibb

##### ClinicalTrials.gov Identifier :

NCT02477826

##### Other Study ID Numbers :

CA209-227, 2014-003630-23

##### First Posted :

June 23, 2015

##### Last Update Posted :

September 21, 2021

##### Last Verified :

September 2021

**Additional relevant  
MeSH terms :**

*Lung Neoplasms*

*Carcinoma, Non-Small-Cell*

*Lung*

*Respiratory Tract Neoplasms*

*Thoracic Neoplasms*

*Neoplasms by Site*

*Neoplasms*

*Lung Diseases*

*Respiratory Tract Diseases*

*Carcinoma, Bronchogenic*

*Bronchial Neoplasms*