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COMPLETED ⓘ

A Dose Frequency Optimization,Trial of Nivolumab 240 mg Every 2 Weeks vs Nivolumab 480 mg Every 4 Weeks in Subjects With Advanced or Metastatic Non-small Cell Lung Cancer Who Received Up to 12 Months of Nivolumab at 3 mg/kg or 240 mg Every 2 Weeks (CheckMate 384)

ClinicalTrials.gov ID ⓘ **NCT02713867**

Sponsor ⓘ Bristol-Myers Squibb

Information provided by ⓘ Bristol-Myers Squibb (Responsible Party)

Last Update Posted ⓘ 2023-02-14



Study Details

Researcher View

Results Posted

Record History

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
 - To view one version of the study record, click the submitted date.
 - To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2016-03-15	None (earliest version on record)
☐	2	2016-03-21	- Study Status - Arms and Interventions - Study Identification
☐	3	2016-04-06	- Study Status - Contacts/Locations - References
☐	4	2016-04-12	- Study Status - Contacts/Locations
☐	5	2016-04-13	Study Status
☐	6	2016-04-26	- Recruitment Status - Study Status - Contacts/Locations
☐	7	2016-05-02	Study Status
☐	8	2016-05-10	- Study Status - Contacts/Locations
☐	9	2016-05-17	Study Status
☐	10	2016-05-26	- Study Status - Contacts/Locations
☐	11	2016-06-09	- Study Status - Contacts/Locations
☐	12	2016-06-13	Study Status
☐	13	2016-06-24	- Study Status - Contacts/Locations
☐	14	2016-06-28	Study Status
☐	15	2016-07-11	- Study Status - Contacts/Locations
☐	16	2016-07-13	Study Status
☐	17	2016-07-26	- Study Status - Contacts/Locations
☐	18	2016-07-27	Study Status
☐	19	2016-08-08	- Study Status - Contacts/Locations
☐	20	2016-08-10	Study Status
☐	21	2016-08-30	- Study Status - Study Identification - Eligibility - Contacts/Locations
☐	22	2016-09-07	- Study Status - Contacts/Locations
☐	23	2016-09-15	Study Status
☐	24	2016-09-23	- Study Status - Contacts/Locations

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☐	25	2016-10-07	- Study Status - Contacts/Locations
☐	26	2016-10-21	- Study Status - Contacts/Locations
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☐	32	2017-01-05	- Study Status - Contacts/Locations
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☐	35	2017-02-16	- Study Status - Contacts/Locations
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☐	40	2017-05-24	- Study Status - Contacts/Locations
☐	41	2017-06-08	- Study Status - Contacts/Locations
☐	42	2017-06-26	- Study Status - Contacts/Locations
☐	43	2017-07-24	- Study Status - Contacts/Locations
☐	44	2017-08-02	- Study Status - Contacts/Locations
☐	45	2017-09-01	- Study Status - Contacts/Locations
☐	46	2017-10-03	Study Status
☐	47	2017-11-03	- Study Status - Contacts/Locations
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☐	49	2018-02-02	- Study Status - Contacts/Locations
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☐	51	2018-09-14	- Study Status - Study Design - Outcome Measures - Study Description - Arms and Interventions - Contacts/Locations - References
☐	52	2020-06-02	- Study Status - Contacts/Locations - Study Design - Outcome Measures - Participant Flow - Baseline Characteristics - Adverse Events - More Information - Document Section
☐	53	2022-03-11	- Recruitment Status - Study Status - Contacts/Locations
☐	54	2023-01-18	- Study Status - Outcome Measures - Contacts/Locations - Participant Flow - Baseline Characteristics - Adverse Events - Document Section

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Version 2: 2016-03-21

Study Details

Study Identification

Unique Protocol ID	CA209-384
Brief Title	A Dose Frequency Optimization,Trial of Nivolumab 240 mg Every 2 Weeks vs Nivolumab 480 mg Every 4 Weeks in Subjects With Advanced or Metastatic Non-small Cell Lung Cancer Who Received 4 Months of Nivolumab at 3 mg/kg or 240 mg Every 2 Weeks
Official Title	A Dose Frequency Optimization, Phase IIIB/IV Trial of Nivolumab 240 mg Every 2 Weeks vs Nivolumab 480 mg Every 4 Weeks in Subjects With Advanced or Metastatic Non-small Cell Lung Cancer Who Received 4 Months of Nivolumab at 3 mg/kg or 240 mg Every 2 Weeks
Secondary IDs	

Study Status

Record Verification	2016-03
Overall Status	Not yet recruiting
Study Start	2016-03
Primary Completion	2018-05 [Estimated]
Study Completion	2022-05 [Estimated]
First Submitted	2016-03-11
First Submitted that Met QC Criteria	2016-03-15
First Posted	2016-03-21
Last Update Submitted that Met QC Criteria	2016-03-21
Last Update Posted	2016-03-22 [Estimated]

Sponsor/Collaborators

Sponsor	Bristol-Myers Squibb
Responsible Party	Sponsor
Collaborators	

Oversight

U.S. FDA-regulated Drug	
U.S. FDA-regulated Device	
Data Monitoring	Yes

Study Description

Brief Summary	The primary objective of this study is to show that PFS (progress-free survival) rate at 6 months and at 1 year after randomization, of Nivolumab 480 mg every 4 weeks is non-inferior to nivolumab 240 mg every 2 weeks in subjects with advanced/metastatic (Stage IIIB/IV) NSCLC (non-Sq and Sq).
Detailed Description	

Conditions

Condition	Lung Cancer
Keywords	

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 3
Interventional Study Model	Parallel Assignment
Interventional Model Description	
Number of Arms	2
Masking	None (Open Label)
Masking Description	
Allocation	Randomized
Enrollment	620 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Nivolumab 240 mg	Biological: Nivolumab
Nivolumab 240 mg Every 2 Weeks	
Experimental: Nivolumab 480 mg	Biological: Nivolumab
Nivolumab 480 mg Every 4 Weeks	

Outcome Measures

Primary Outcome Measures	1. Progression Free Survival (PFS) rate at 6 months after randomization [Time Frame: 6 months after randomization] 2. Progression Free Survival (PFS) rate at 12 months after randomization [Time Frame: 12 months after randomization]
Secondary Outcome Measures	1. Progression Free Survival (PFS) rate after randomization by tumor histology and by response criteria [Time Frame: 1 year after randomization] 2. Progression Free Survival (PFS) rate [Time Frame: 2 years after randomization] 3. Overall Survival Rate (OSR) [Time Frame: Every year up to 5 years after randomization] 4. Safety and Tolerability assessed by the incidence and severity of adverse events (AEs) [Time Frame: Randomization Till End of Study (Up to 5 years)]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	For more information regarding Bristol-Myers Squibb Clinical Trial participation, please visit: www.BMSStudyConnect.com Inclusion Criteria: - Histologically or cytologically documented Sq- or non-SqNSCLC (Stage IIIB/IV), or recurrent or progressive disease following multimodal therapy - SD, PR or CR during pretreatment phase with nivolumab 3 mg/kg or 240 mg every 2 weeks (4 months) - Measurable disease before start of pre-study nivolumab treatment - ECOG PS 0-2 Exclusion Criteria: - Carcinomatous meningitis - Untreated, symptomatic CNS metastases - Symptomatic interstitial lung disease Other protocol defined inclusion/exclusion criteria could apply

Contacts/Locations

Central Contact Person	Name Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email Email Clinical.Trials@bms.com Name First line of the email MUST contain NCT # and Site #.
Study Officials	Name Bristol-Myers Squibb Role Study Director Affiliation Bristol-Myers Squibb
Location	

IPD Sharing

Available IPD/Information	
IPD information	

References

Citations	
Links	BMS Clinical Trial Educational Resource

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