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)

This study is currently recruiting participants. (see Contacts and Locations)

Verified September 2016 by Bristol-Myers Squibb

Sponsor:
Bristol-Myers Squibb

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

ClinicalTrials.gov Identifier:
NCT02713867

First received: March 11, 2016
Last updated: September 15, 2016
Last verified: September 2016
History of Changes

Purpose

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).

Condition	Intervention	Phase
Lung Cancer	Biological: Nivolumab	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

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 up to 12 Months of Nivolumab at 3 mg/kg or 240 mg Every 2 Weeks

Resource links provided by NLM:

Genetics Home Reference related topics: lung cancer

MedlinePlus related topics: Cancer Lung Cancer

Drug Information available for: Nivolumab

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- Progression Free Survival (PFS) rate at 6 months after randomization [Time Frame: 6 months after randomization] [Designated as safety issue: No]
- Progression Free Survival (PFS) rate at 12 months after randomization [Time Frame: 12 months after randomization] [Designated as safety issue: No]

Secondary Outcome Measures:

- Progression Free Survival (PFS) rate after randomization by tumor histology and by response criteria [Time Frame: 1 year after randomization] [Designated as safety issue: No]
- Progression Free Survival (PFS) rate [Time Frame: 2 years after randomization] [Designated as safety issue: No]
- Overall Survival Rate (OSR) [Time Frame: Every year up to 5 years after randomization] [Designated as safety issue: No]
- Safety and Tolerability assessed by the incidence and severity of adverse events (AEs) [Time Frame: Randomization Till End of Study (Up to 5 years)] [Designated as safety issue: Yes]

Estimated Enrollment: 620
Study Start Date: April 2016

Estimated Study Completion Date: June 2022
Estimated Primary Completion Date: May 2018 (Final data collection date for primary outcome measure)

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

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
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 Squamous or non-Squamous Non-small cell lung cancer (NSCLC) (Stage IIIB/IV), or recurrent or progressive disease following multimodal therapy
- Patients must have received pre-study nivolumab for up to 12 months and have 2 consecutive tumor assessments confirming Complete response (CR), Partial response (PR), or Stable disease (SD)
- Measurable disease before start of pre-study nivolumab treatment
- Eastern Cooperative Oncology Group (ECOG) Performance status (PS) 0-2

Exclusion Criteria:

- Carcinomatous meningitis
- Untreated, symptomatic Central nervous system (CNS) metastases
- Symptomatic interstitial lung disease

Other protocol defined inclusion/exclusion criteria could apply

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02713867

Contacts

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email: Clinical.Trials@bms.cor

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

Show 122 Study Locations

Sponsors and Collaborators

Bristol-Myers Squibb

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

Additional Information:

BMS Clinical Trial Information

BMS clinical trial educational resource

Investigator Inquiry form

FDA Safety Alerts and Recalls

Responsible Party: Bristol-Myers Squibb
ClinicalTrials.gov Identifier: NCT02713867 History of Changes
Other Study ID Numbers: **CA209-384**
Study First Received: March 11, 2016
Last Updated: September 15, 2016
Health Authority: Australia: Department of Health and Ageing Therapeutic Goods Administration
Austria: Agency for Health and Food Safety
Canada: Health Canada
Germany: Paul-Ehrlich-Institut

France: Agence Nationale de Sécurité du Médicament et des produits de santé
Ireland: Health Products Regulatory Authority
Italy: The Italian Medicines Agency
Spain: Agencia Española de Medicamentos y Productos Sanitarios
United States: Food and Drug Administration

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
Nivolumab
Antibodies, Monoclonal
Antineoplastic Agents
Immunologic Factors
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on September 23, 2016