Trial record **1 of 1** for: CA209-234

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Pattern of Use and Safety/Effectiveness of Nivolumab in Routine Oncology Practice

This study is currently recruiting participants.

See Contacts and Locations

Verified June 2017 by Bristol-Myers Squibb

Sponsor:
Bristol-Myers Squibb

ClinicalTrials.gov Identifier:
NCT02847728

First Posted: July 28, 2016
Last Update Posted: June 27, 2017

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

Full Text View | Tabular View | No Study Results Posted | Disclaimer
How to Read a Study Record

Purpose

This is an observational, multicenter study in patients treated with nivolumab for the approved indications of melanoma and lung cancer in Australia, the EU, Switzerland, and the United States (US). Targeted

countries in the EU for study participation include Austria, Belgium, France, Germany, Italy, Spain, and the United Kingdom (UK). Study objectives are to assess the safety experience, survival, adverse event management, and outcomes of adverse events associated with nivolumab in routine oncology care facilities.

Condition
Melanoma
Lung Cancer

Study Type: Observational
Study Design: Observational Model: Other
Time Perspective: Prospective

Official Title: Pattern of Use and Safety/Effectiveness of Nivolumab in Routine Oncology Practice

Resource links provided by NLM:

Genetics Home Reference related topics: lung cancer

MedlinePlus related topics: Melanoma

Drug Information available for: Nivolumab

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- Incidence rate of and severity of immune-related pneumonitis - Melanoma [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related colitis- Melanoma [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related hepatitis - Melanoma [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related nephritis/renal dysfunction - Melanoma [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related endocrinopathies - Melanoma [Time Frame: up to nine years]

- Incidence rate of and severity of immune-related rash (including toxic epidermal necrolysis) - Melanoma [Time Frame: up to nine years]
- Incidence rate of and severity of other immune-related adverse events (eg, uveitis, pancreatitis, demyelination, Guillain-Barre Syndrome, myasthenic syndrome, and encephalitis) - Melanoma [Time Frame: up to nine years]
- Incidence rate of and severity of severe infusion reactions- Melanoma [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related pneumonitis - Lung Cancer [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related colitis - Lung Cancer [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related hepatitis - Lung Cancer [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related nephritis/renal dysfunction - Lung Cancer [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related endocrinopathies - Lung Cancer [Time Frame: up to nine years]
- Incidence rate of and severity of other immune related adverse events (eg, uveitis, pancreatitis, demyelination, Guillain-Barre Syndrome, myasthenic syndrome, and encephalitis) - Lung Cancer [Time Frame: up to nine years]
- Incidence rate of and severity of severe infusion reactions - Lung Cancer [Time Frame: up to nine years]
- Incidence rate of and severity of immune-related rash (including toxic epidermal necrolysis), - Lung Cancer [Time Frame: up to nine years]

Secondary Outcome Measures:

- Adverse Events [Time Frame: Up to nine years]

  Other nivolumab treatment-related AEs

- Management of Immune-related AEs: [Time Frame: Up to nine years]
- Outcomes of Immune-related AEs: [Time Frame: Up to nine years]
- Overall Survival: [Time Frame: Up to nine years]

  1-, 2-, 3-, 4-, and 5-year overall and median survival

- Nivolumab treatment pattern [Time Frame: Up to nine years]

Estimated Enrollment:	1200
Study Start Date:	July 2016
Estimated Study Completion Date:	December 2024
Estimated Primary Completion Date:	March 2024 (Final data collection date for primary outcome measure)

Groups/Cohorts

Single Arm Design

The study encompasses a single arm design with 400 adults treated with nivolumab for histologically or cytologically confirmed melanoma and 800 adults treated with nivolumab for histologically or cytologically confirmed lung cancer.

Detailed Description:

This is an observational, multicenter study in patients treated with nivolumab for the approved indications of melanoma and lung cancer in Australia, the EU, Switzerland, and the United States (US). Targeted countries in the EU for study participation include Austria, Belgium, France, Germany, Italy, Spain, and the United Kingdom (UK). Study objectives are to assess the safety experience, survival, adverse event management, and outcomes of adverse events associated with nivolumab in routine oncology care facilities. The study will be started in 2016, and data collection will be continued until March 2024.

Eligibility

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, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Probability Sample

Study Population

The study population consists of 400 adults treated with nivolumab for histologically or cytologically confirmed melanoma and 800 adults treated with nivolumab for histologically or cytologically confirmed lung cancer in accordance with the approved indications in Australia, the

EU, Switzerland, and the US. Target EU countries for patient enrollment include Austria, Belgium, France, Germany, Italy, Spain, and the UK. Patients who begin treatment with nivolumab for the first time will be enrolled in accordance with the approved indications and whose treatment strategy was determined independently from consideration of study participation. Treatment will be determined at the treating physician's discretion and with the patient's consent.

Criteria

Inclusion Criteria:

- Age ≥18
- Histologically or cytologically confirmed diagnosis of melanoma (including uveal melanoma) or lung cancer
- Treatment with commercial nivolumab for the first time, alone or in combination with ipilimumab, for the approved indications of nivolumab within 14 days before informed consent for this study OR in the case where treatment has not yet been initiated, documentation that the treatment strategy is determined before an informed consent to study participation, and treatment is initiated within 28 days after informed consent

Exclusion Criteria:

- Prior participation in a clinical trial within the past 4 weeks
- Previously treated with anti-PD-1, anti-PD-L1, or anti-PD-L2 antibodies
- Previously treated with anti-CTLA-4 for lung cancer
- Current or pending participation in a clinical trial
- Current or pending systemic treatment for cancer other than melanoma and lung cancer
- Inability to comply with the study protocol

Other protocol defined inclusion and exclusion criteria could apply

Contacts and Locations

Information from the National Library of Medicine NIH NLM

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): ***NCT02847728***

Contacts

Contact: Recruiting sites have contact information. Please contact sites directly. If there in no con

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

Show 81 Study Locations

Sponsors and Collaborators

Bristol-Myers Squibb

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

Additional Information:

Investigator Inquiry Form EXIT

FDA Safety Alerts and Recalls EXIT

BMS Clinical Trial Information EXIT

Responsible Party:	Bristol-Myers Squibb
ClinicalTrials.gov Identifier:	NCT02847728 History of Changes
Other Study ID Numbers:	**CA209-234**
First Submitted:	June 28, 2016
First Posted:	July 28, 2016
Last Update Posted:	June 27, 2017
Last Verified:	June 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Additional relevant MeSH terms:

Nivolumab

Antineoplastic Agents