Trial record **1 of 1** for: 2016-003729-41

Previous Study | Return to List | Next Study

An Investigational Immuno-therapy Study of Nivolumab Combined With Ipilimumab Compared to Nivolumab by Itself After Complete Surgical Removal of Stage IIIb/c/d or Stage IV Melanoma (CheckMate 915)

This study is currently recruiting participants.

See Contacts and Locations

Verified October 2017 by *Bristol-Myers Squibb*

Sponsor:
Bristol-Myers Squibb

ClinicalTrials.gov Identifier:
NCT03068455

First Posted: March 1, 2017
Last Update Posted: October 4, 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

The purpose of this study is to determine whether an investigational immunotherapy Nivolumab, when combined with Ipilimumab, is more effective than Nivolumab by itself, in delaying the return of cancer in patients who have had a complete surgical removal of stage IIIb/c/d or stage IV Melanoma

Condition	Intervention	Phase
Melanoma	Biological: nivolumab Biological: ipilimumab	Phase 3

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double (Participant, Investigator)
Primary Purpose: Treatment

Official Title: A Phase 3, Randomized Study of Adjuvant Immunotherapy With Nivolumab Combined With Ipilimumab Versus Nivolumab Monotherapy After Complete Resection of Stage IIIb/c/d or Stage IV Melanoma

Resource links provided by NLM:

MedlinePlus related topics: Melanoma

Drug Information available for: Ipilimumab Nivolumab

Genetic and Rare Diseases Information Center resources: Carcinoid Tumor Neuroepithelioma

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- Recurrence-free survival (RFS) [Time Frame: Approximately 3 years]

  measured by time

Secondary Outcome Measures:

- Overall Survival (OS) [Time Frame: Up to 5 years]

  measured by time

- PD-L1 expression [Time Frame: Approximately 3 years]

  measured by immunoassay

Estimated Enrollment:	900
Actual Study Start Date:	April 7, 2017
Estimated Study Completion Date:	February 17, 2023
Estimated Primary Completion Date:	November 8, 2020 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: nivolumab + ipilimumab Specified Dose on Specified Days	Biological: nivolumab Specified Dose on Specified Days Other Names: • Opdivo • BMS-936558 Biological: ipilimumab Specified Dose on Specified Days Other Names: • Yervoy • BMS-734016
Experimental: nivolumab Specified Dose on Specified Days	Biological: nivolumab Specified Dose on Specified Days Other Names: • Opdivo • BMS-936558

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:	15 Years and older (Child, Adult, Senior)
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:

- Completely surgically resected stage IIIb/c/d or stage IV melanoma within 12 weeks of participation in study.
- Must have full activity or, if limited, must be able to walk and carry out activities such as light house work or office work
- No prior anti-cancer treatment for melanoma (except surgery for the melanoma lesion(s) and/or except for adjuvant radiation therapy (RT) after neurosurgical resection for central nervous system (CNS) lesions)

Exclusion Criteria:

- History of uveal melanoma
- Weight less than or equal to 40 kg
- Patients with active, known or suspected autoimmune disease
- Prior treatment with interferon (if complete < 6 months prior to participation in study), anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, 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 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): ***NCT03068455***

Contacts

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no

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

Show 132 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

FDA Safety Alerts and Recalls

BMS Clinical Trial Patient Recruiting

Investigator Inquiry Form

Responsible Party:	Bristol-Myers Squibb
ClinicalTrials.gov Identifier:	NCT03068455 History of Changes
Other Study ID Numbers:	CA209-915
	2016-003729-41 (EudraCT Number)
First Submitted:	February 27, 2017
First Posted:	March 1, 2017
Last Update Posted:	October 4, 2017
Last Verified:	October 2017

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Melanoma
Neuroendocrine Tumors
Neuroectodermal Tumors
Neoplasms, Germ Cell and Embryonal
Neoplasms by Histologic Type
Neoplasms
Neoplasms, Nerve Tissue
Nevi and Melanomas
Nivolumab
Antibodies, Monoclonal
Antineoplastic Agents
Immunologic Factors
Physiological Effects of Drugs