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Completed ⓘ

Dose-escalation Study of Combination BMS-936558 (MDX-1106) and Ipilimumab in Subjects With Unresectable Stage III or Stage IV Malignant Melanoma

ClinicalTrials.gov ID ⓘ NCT01024231

Sponsor ⓘ Bristol-Myers Squibb

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

Last Update Posted ⓘ 2021-03-22

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Study Overview

Brief Summary

The purpose of this study is to determine the safety and tolerability of treatment with BMS-936558 (MDX-1106) in combination with Ipilimumab (BMS-734016) when given at the same time or as a sequenced regimen in subjects with unresectable Stage III or Stage IV malignant melanoma (MEL)

Official Title

A Phase 1b, Open-label, Multicenter, Multidose, Dose-escalation Study of BMS-936558 (MDX-1106) in Combination With Ipilimumab in Subjects With Unresectable Stage III or Stage IV Malignant Melanoma

Conditions ⓘ

Malignant Melanoma

Intervention / Treatment ⓘ

- Drug: BMS-936558 (MDX1106-04)

Study Start (Actual) ⓘ

2009-12-14

Primary Completion (Actual) ⓘ

2014-02-04

Study Completion (Actual) ⓘ

2019-04-01

Enrollment (Actual) ⓘ

127

Study Type ⓘ

Interventional

Phase ⓘ

Phase 1



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Conditions

[Malignant Melanoma](#)

Intervention / Treatment

- Drug: BMS-936558 (MDX1106-04)
- Drug: Ipilimumab

Other Study ID Numbers

- CA209-004
- (MDX1106-04) (Other Identifier) (OTHER: Medarex)

127

Study Type

Interventional

Phase

Phase 1

Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](#) related topics: [Melanoma](#)[MedlinePlus](#) related topics: [Melanoma](#)[Genetic and Rare Diseases Information Center](#) resources: [Neuroendocrine Tumor](#) [Neuroepithelioma](#)[Drug Information](#) available for: [Ipilimumab](#) [Nivolumab](#)[FDA Drug and Device Resources](#)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](#).

This study has 4 locations

United States

Connecticut Locations

- New Haven, Connecticut, United States, 06520
Yale University School Of Medicine

District of Columbia Locations

- Washington, District of Columbia, United States, 20007
Medstar Georgetown-Lombardi Comprehensive Cancer Center

New York Locations

- New York, New York, United States, 11065
Memorial Sloan Kettering Nassau

Pennsylvania Locations

- Pittsburgh, Pennsylvania, United States, 15232
Hillman Cancer Research Pavilion



Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

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Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#).

Eligibility Criteria

Description

For more information regarding BMS clinical trial participation, please visit www.BMSStudyConnect.com

Inclusion Criteria:

- Histologic diagnosis of malignant melanoma (MEL)
- Measurable unresectable Stage III or IV MEL
- ECOG performance status score of 0 or 1
- Life expectancy ≥ 4 months
- For those enrolled in amendment 5 and later, tumor tissue (archival or recent acquisition) must be available
- For Cohorts 1-5, subjects may have been treated with up to 3 prior systemic standard treatments for metastatic melanoma not including any post-incisional adjuvant therapy. Subjects may be treatment naïve. All metastatic melanoma regardless of primary site of disease will be allowed
- For Cohorts 6-7, subjects may have been treated with up to 3 prior systemic standard treatments for metastatic melanoma; this does not include any post-incisional adjuvant therapy. Specifically, subjects must have received ≥ 3 doses of Ipilimumab therapy and the last dose having been administered within 4-12 weeks of initiation of study treatment

Exclusion Criteria:

- History of severe hypersensitivity reactions to other mAbs
- Prior malignancy active within the previous 2 years except for localized cancers that are considered to have been cured and in the opinion of the investigator present a low risk for recurrence
- Active autoimmune disease or a history of known or suspected autoimmune disease
- History of recently active diverticulitis or symptomatic peptic ulcer disease and history of adrenal insufficiency
- Regular narcotic analgesia
- Active, untreated central nervous system metastasis
- For subjects enrolled in Cohorts 1-5, prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-CTLA-4 antibody
- For subjects enrolled in Cohorts 6-7, prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-CD137 antibodies
- Any non-oncology vaccine therapy used for prevention of infectious disease
- Concomitant therapy with any other anti-cancer therapy, concurrent medical conditions requiring use of immunosuppressive medications or use of other investigational drugs
- Positive tests for human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), hepatitis B, hepatitis C
- Subjects weighing ≥ 125 kg are excluded from Cohort 5
- Subjects in Cohorts 6 and 7 must have received Ipilimumab monotherapy immediately prior to study entry, but must not have received that Ipilimumab as part of a clinical trial
- Subjects with ocular melanoma are excluded from Cohort 8

Ages Eligible for Study ¹

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study ¹

All

Accepts Healthy Volunteers ¹

No

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- Positive tests for human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), hepatitis B, hepatitis C
- Subjects weighing ≥ 125 kg are excluded from Cohort 5
- Subjects in Cohorts 6 and 7 must have received Ipilimumab monotherapy immediately prior to study entry, but must not have received that Ipilimumab as part of a clinical trial
- Subjects with ocular melanoma are excluded from Cohort 8

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

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How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : Non-Randomized

Interventional Model ⓘ : Single Group Assignment

Masking ⓘ : None (Open Label)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: Cohort 1: BMS-936558 (0.3 mg/kg)+Ipilimumab (3 mg/kg) BMS-936558 (MDX1106-04) 0.3 mg/kg solution, 60 minutes intravenous infusion every 3 (q3) weeks for 21 weeks in induction and every 12 (q12) weeks for 84 weeks in maintenance Ipilimumab (BMS-734016) 3 mg/kg solution, 90 minutes intravenous infusion q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance	Drug: BMS-936558 (MDX1106-04) • Other Names: ◦ Nivolumab Drug: Ipilimumab • Other Names: ◦ BMS-734016
Experimental: Cohort 2: BMS-936558 (1 mg/kg)+Ipilimumab (3 mg/kg) Ipilimumab (BMS-734016) 3 mg/kg solution, 90 minutes intravenous infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance BMS-936558 (MDX1106-04) 1 mg/kg solution, 60 minutes intravenous infusion, q3 weeks for	Drug: BMS-936558 (MDX1106-04) • Other Names: ◦ Nivolumab Drug: Ipilimumab • Other Names: ◦ BMS-734016

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infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance

BMS-936558 (MDX1106-04) 1 mg/kg solution, 60 minutes intravenous infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance

Experimental: Cohort 3: BMS-936558 (3 mg/kg)+Ipilimumab (3 mg/kg)

Ipilimumab (BMS-734016) 3 mg/kg solution, 90 minutes intravenous infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance

BMS-936558 (MDX1106-04) 3 mg/kg solution, 60 minutes intravenous infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance

Drug: BMS-936558 (MDX1106-04)

- Other Names:
 - Nivolumab

Drug: Ipilimumab

- Other Names:
 - BMS-734016

Experimental: Cohort 4: BMS-936558 (10 mg/kg)+Ipilimumab (3 mg/kg)

BMS-936558 (MDX1106-04) 10 mg/kg solution, 60 minutes intravenous infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance

Ipilimumab (BMS-734016) 3 mg/kg solution, 90 minutes intravenous infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance

Drug: BMS-936558 (MDX1106-04)

- Other Names:
 - Nivolumab

Drug: Ipilimumab

- Other Names:
 - BMS-734016

Experimental: Cohort 5: BMS-936558 (10 mg/kg)+Ipilimumab (10 mg/kg)

BMS-936558 (MDX1106-04) 10 mg/kg solution, 60 minutes intravenous infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance

Ipilimumab (BMS-734016) 10 mg/kg solution, 90 minutes intravenous infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance

Drug: BMS-936558 (MDX1106-04)

- Other Names:
 - Nivolumab

Drug: Ipilimumab

- Other Names:
 - BMS-734016

Experimental: Cohort 6: BMS-

Drug: BMS-936558 (MDX1106-04)

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mg/kg solution, 90 minutes intravenous infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance

Experimental: Cohort 6: BMS-936558 (1 mg/kg)

BMS-936558 (MDX1106-04) 1 mg/kg solution, 60 minutes intravenous infusion, once q2 weeks for a total maximal duration of 96 weeks

Drug: BMS-936558 (MDX1106-04)

- Other Names:
 - Nivolumab

Experimental: Cohort 7: BMS-936558 (3 mg/kg)

BMS-936558 (MDX1106-04) 3 mg/kg solution, 60 minutes intravenous infusion, once q2 weeks for a total maximal duration of 96 weeks

Drug: BMS-936558 (MDX1106-04)

- Other Names:
 - Nivolumab

Experimental: Cohort 8: Nivolumab+Ipilimumab

Nivolumab 1 mg/kg and Ipilimumab 3 mg/kg solution intravenously q3 weeks, 4 doses for 12 weeks

Followed by Nivolumab 3 mg/kg solution alone intravenously q2 weeks, 48 doses for a maximum of 96 weeks

Drug: BMS-936558 (MDX1106-04)

- Other Names:
 - Nivolumab

Drug: Ipilimumab

- Other Names:
 - BMS-734016

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With an Adverse Event (AE)	incidence of all cause and treatment related adverse events	Up to 3 years
Number of Participants With a Serious Adverse Event (AE)	incidence of all cause and treatment related serious adverse events	Up to 3 years
Number of Participants With an Adverse Event (AE) Which Lead to Discontinuation	incidence of all cause and treatment related adverse events which lead to discontinuation	Up to 3 years
Number of Deaths	incidence of all cause and treatment related deaths	Up to 3 years

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With an Adverse Event (AE) Which Lead to Discontinuation	lead to discontinuation	
Number of Deaths	incidence of all cause and treatment related deaths	Up to 3 years
Number of Participants With Select AEs	incidence of all cause and treatment related Adverse events in certain organ systems	Up to 3 years
Laboratory Abnormalities: Specific Liver Tests	Number of Participants with On-Treatment Laboratory Abnormalities in Specific Liver Tests Aspartate aminotransferase (AST) Alanine aminotransferase (ALT) Upper Limit of Normal (ULN)	Up to 3 years
Laboratory Abnormalities: Specific Thyroid Tests	Number of Participants with On-Treatment Laboratory Abnormalities in Specific Thyroid Tests Free T3 (FT3) Free T4 (FT4) Lower Limit of Normal (LLN)	Up to 3 years

Secondary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Objective Response Rate	the total number of participants whose best overall response (BOR) is either irCR or irPR divided by the total number of response-evaluable participants.	Up to 3 years
Time to Response	the time from the first dose of study drug until the first documentation of irCR or irPR, as related to current database lock date or most current tumor measurement	Up to 3 Years
Duration of Response	the time from the first documented response (irCR or irPR) until progression or death, whichever occurs first. For participants who did not progress or die, duration of response will be censored on the date of the last tumor assessment.	from the first documented response (irCR or irPR) until progression or death
Progression Free Survival	the time from the first dose to the first observation of disease progression or death due to any cause. If a participant has not progressed or died at the time of analysis, PFS will be censored on the date of the last disease assessment. Participants who did not have any on-study tumor assessments and did not die will be censored on the date of the first dose of study medication.	156 weeks
Number of Participants With an Anti-Drug Antibody (ADA) Response for Nivolumab (Nivo) and Ipilimumab (Ipi)	Serum samples will be collected to evaluate the development of antibodies to BMS-936558 and to ipilimumab.	Up to 3 years
Peak and Trough Concentrations	The peak and trough concentrations of BMS-936558 (MDX-1106) and ipilimumab in participants with quantifiable data	Up to 64 Weeks

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Peak and Trough Concentrations	The peak and trough concentrations of BMS-936558 (MDX-1106) and ipilimumab in participants with quantifiable data	Up to 64 Weeks
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Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Bristol-Myers Squibb

Collaborators ⓘ

- Medarex
- Ono Pharma USA Inc

Investigators ⓘ

- Study Director: Bristol-Myers Squibb, Bristol-Myers Squibb

Publications

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- [Callahan MK, Kluger H, Postow MA, Segal NH, Lesokhin A, Atkins MB, Kirkwood JM, Krishnan S, Bhore R, Horak C, Wolchok JD, Sznol M. Nivolumab Plus Ipilimumab in Patients With Advanced Melanoma: Updated Survival, Response, and Safety Data in a Phase I Dose-Escalation Study. J Clin Oncol. 2018 Feb 1;36\(4\):391-398. doi: 10.1200/JCO.2017.72.2850. Epub 2017 Oct 17. \[↗\]\(#\)](#)
- [Nguyen AT, Elia M, Materin MA, Sznol M, Chow J. Cyclosporine for Dry Eye Associated With Nivolumab: A Case Progressing to Corneal Perforation. Cornea. 2016 Mar;35\(3\):399-401. doi: 10.1097/ICO.0000000000000724. \[↗\]\(#\)](#)
- [Wolchok JD, Kluger H, Callahan MK, Postow MA, Rizvi NA, Lesokhin AM, Segal NH, Ariyan CE, Gordon RA, Reed K, Burke MM, Caldwell A, Kronenberg SA, Agunwamba BU, Zhang X, Lowy I, Inzunza HD, Feely W, Horak CE, Hong Q, Korman AJ, Wigginton JM, Gupta A, Sznol M. Nivolumab plus ipilimumab in advanced melanoma. N Engl J Med. 2013 Jul 11;369\(2\):122-33. doi: 10.1056/NEJMoa1302369. Epub 2013 Jun 2. \[↗\]\(#\)](#)

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2009-12-01

First Submitted that Met QC Criteria ⓘ

2009-12-01

First Posted (Estimated) ⓘ

2009-12-02

Results Reporting Dates

Results First Submitted ⓘ

2020-08-28

Results First Submitted that Met QC Criteria ⓘ

2021-03-19

Results First Posted ⓘ

2021-03-22

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2021-03-19

Last Update Posted ⓘ

2021-03-22

Last Verified ⓘ

2021-03-22

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Results First Submitted that Met QC Criteria

2021-03-19

Results First Posted

2021-03-22

Last Update Submitted that Met QC Criteria

2021-03-19

Last Update Posted

2021-03-22

Last Verified

2021-03

More Information

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Terms related to this study

Additional Relevant MeSH Terms

Neuroendocrine Tumors
Neuroectodermal Tumors
Neoplasms, Germ Cell and Embryonal
Neoplasms by Histologic Type
Neoplasms
Neoplasms, Nerve Tissue
Nevi and Melanomas
Skin Neoplasms
Neoplasms by Site
Skin Diseases
Melanoma
Antineoplastic Agents, Immunological
Antineoplastic Agents
Immune Checkpoint Inhibitors
Molecular Mechanisms of Pharmacological Action
Nivolumab
Ipilimumab

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Study Documents Provided by Bristol-Myers Squibb

- [Statistical Analysis Plan](#) [PDF, 6.04MB, 2014-08-20]
- [Study Protocol](#) [PDF, 4.2MB, 2017-05-10]

Helpful Links Provided by Bristol-Myers Squibb

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Neoplasms
Neoplasms, Nerve Tissue
Nevi and Melanomas
Skin Neoplasms
Neoplasms by Site
Skin Diseases
Melanoma
Antineoplastic Agents, Immunological
Antineoplastic Agents
Immune Checkpoint Inhibitors
Molecular Mechanisms of Pharmacological Action
Nivolumab
Ipilimumab

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Study Documents  Provided by Bristol-Myers Squibb

- [Statistical Analysis Plan](#) [PDF, 6.04MB, 2014-08-20]
- [Study Protocol](#) [PDF, 4.2MB, 2017-05-10]

Helpful Links Provided by Bristol-Myers Squibb

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