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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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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	2009-12-01	<ul style="list-style-type: none">• None (earliest version on record)
☐	2	2009-12-16	<ul style="list-style-type: none">• Study Status• Study Design• Contacts/Locations• References
☐	3	2010-01-04	<ul style="list-style-type: none">• Study Status
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☐	3	2010-01-04	<ul style="list-style-type: none"> Study Status Arms and Interventions
☐	4	2010-01-12	<ul style="list-style-type: none"> Study Status
☐	5	2010-02-03	<ul style="list-style-type: none"> Study Status
☐	6	2010-02-18	<ul style="list-style-type: none"> Recruitment Status Study Status Contacts/Locations
☐	7	2010-03-04	<ul style="list-style-type: none"> Study Status
☐	8	2010-03-17	<ul style="list-style-type: none"> Study Status
☐	9	2010-03-31	<ul style="list-style-type: none"> Study Status
☐	10	2010-04-13	<ul style="list-style-type: none"> Study Status
☐	11	2010-04-27	<ul style="list-style-type: none"> Study Status
☐	12	2010-05-21	<ul style="list-style-type: none"> Study Status
☐	13	2010-06-14	<ul style="list-style-type: none"> Study Status
☐	14	2010-06-29	<ul style="list-style-type: none"> Study Status
☐	15	2010-07-26	<ul style="list-style-type: none"> Study Status
☐	16	2010-08-03	<ul style="list-style-type: none"> Study Status
☐	17	2010-08-11	<ul style="list-style-type: none"> Study Status
☐	18	2010-08-30	<ul style="list-style-type: none"> Study Status
☐	19	2010-09-13	<ul style="list-style-type: none"> Study Status
☐	20	2010-10-04	<ul style="list-style-type: none"> Study Status
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☐	22	2010-11-15	<ul style="list-style-type: none"> Study Status Study Design Arms and Interventions
☐	23	2010-12-02	<ul style="list-style-type: none"> Study Status Study Design
☐	24	2011-01-06	<ul style="list-style-type: none"> Study Status
☐	25	2011-01-24	<ul style="list-style-type: none"> Study Status
☐	26	2011-02-10	<ul style="list-style-type: none"> Study Status
☐	27	2011-02-22	<ul style="list-style-type: none"> Study Status
☐	28	2011-03-08	<ul style="list-style-type: none"> Study Status
☐	29	2011-03-23	<ul style="list-style-type: none"> Study Status
☐	30	2011-04-07	<ul style="list-style-type: none"> Study Status
☐	31	2011-04-28	<ul style="list-style-type: none"> Study Status
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☐	57	2012-04-18	• Study Status • Study Description • Study Design • Arms and Interventions • Outcome Measures • Eligibility
☐	58	2012-04-30	• Study Status
☐	59	2012-06-18	• Study Status • Study Design
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☐	62	2012-12-19	<ul style="list-style-type: none"> Study Status
☐	63	2013-01-18	<ul style="list-style-type: none"> Study Status
☐	64	2013-03-19	<ul style="list-style-type: none"> Study Status Study Design Contacts/Locations References
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☐	69	2013-06-27	<ul style="list-style-type: none"> Study Status Contacts/Locations
☐	70	2013-08-05	<ul style="list-style-type: none"> Study Status Contacts/Locations
☐	71	2013-08-27	<ul style="list-style-type: none"> Study Status
☐	72	2013-09-25	<ul style="list-style-type: none"> Study Status Contacts/Locations
☐	73	2013-10-30	<ul style="list-style-type: none"> Study Status
☐	74	2013-11-28	<ul style="list-style-type: none"> Study Status Contacts/Locations
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☐	78	2014-04-29	<ul style="list-style-type: none"> Study Status
☐	79	2014-06-12	<ul style="list-style-type: none"> Study Status
☐	80	2014-07-09	<ul style="list-style-type: none"> Study Status
☐	81	2015-02-06	<ul style="list-style-type: none"> Study Status
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☐	81	2015-02-06	<ul style="list-style-type: none"> Study Status
☐	82	2015-07-03	<ul style="list-style-type: none"> Study Status
☐	83	2015-11-16	<ul style="list-style-type: none"> Study Status
☐	84	2016-01-06	<ul style="list-style-type: none"> Study Status
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☐	91	2017-11-30	<ul style="list-style-type: none"> Study Status Contacts/Locations
☐	92	2017-12-11	<ul style="list-style-type: none"> Study Status
☐	93	2019-08-07	<ul style="list-style-type: none"> Study Status References
☐	94	2020-03-10	<ul style="list-style-type: none"> Recruitment Status Study Status Contacts/Locations
☐	95	2020-06-15	<ul style="list-style-type: none"> Study Status <div>Results Submission Events (4) +</div>
☐	96	2021-03-19	<ul style="list-style-type: none"> Study Status Study Design Outcome Measures Document Section Participant Flow Baseline Characteristics Outcome Measures (Results) Adverse Events More Information

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Study Details

Study Identification

Unique Protocol ID	CA209-004
Brief Title	Dose-escalation Study of Combination BMS-936558 (MDX-1106) and Ipilimumab in Subjects With Unresectable Stage III or Stage IV Malignant Melanoma
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
Secondary IDs	(MDX1106-04)

Study Status

Record Verification	2010-11
Overall Status	Recruiting
Study Start	2009-12
Primary Completion	2014-08 [Estimated]
Study Completion	2014-08 [Estimated]
First Submitted	2009-12-01
First Submitted that Met QC Criteria	2009-12-01
First Posted	2009-12-02 [Estimated]
Last Update Submitted that Met QC Criteria	2011-10-17
Last Update Posted	2011-10-18 [Estimated]

Sponsor/Collaborators

Sponsor	Bristol-Myers Squibb
Responsible Party	
Collaborators	Medarex Ono Pharma USA Inc

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Medarex
Ono Pharma USA Inc

Oversight**U.S. FDA-regulated Drug****U.S. FDA-regulated Device****Data Monitoring**

Yes

Study Description**Brief Summary**

The purpose of this study is to assess the safety and tolerability of treatment with BMS-936558 (MDX-1106) in combination with ipilimumab in subjects with unresectable Stage III or Stage IV malignant melanoma

Detailed Description**Conditions****Condition**

Malignant Melanoma

Keywords**Study Design****Study Type**

Interventional

Primary Purpose

Treatment

Study Phase

Phase 1

Interventional Study Model

Single Group Assignment

Number of Arms

5

Masking

None (Open Label)

Allocation

Randomized

Enrollment

64 [Estimated]

Arms and Interventions**Arms**

Experimental: C1

BMS-936558: 0.3 mg/kg Ipilimumab: 3 mg/kg

Assigned Interventions

Drug: BMS-936558 (MDX1106-04)

- Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in

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Arms and Interventions

Arms	Assigned Interventions
<p>Experimental: C1</p> <p>BMS-936558: 0.3 mg/kg Ipilimumab: 3 mg/kg</p>	<p>Drug: BMS-936558 (MDX1106-04)</p> <ul style="list-style-type: none"> Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance <p>Drug: Ipilimumab</p> <ul style="list-style-type: none"> Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance Other Names: <ul style="list-style-type: none"> BMS-734016
<p>Experimental: C2</p> <p>BMS-936558: 1 mg/kg Ipilimumab: 3 mg/kg</p>	<p>Drug: BMS-936558 (MDX1106-04)</p> <ul style="list-style-type: none"> Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance <p>Drug: Ipilimumab</p> <ul style="list-style-type: none"> Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance Other Names: <ul style="list-style-type: none"> BMS-734016
<p>Experimental: C3</p> <p>BMS-936558: 3 mg/kg Ipilimumab: 3 mg/kg</p>	<p>Drug: BMS-936558 (MDX1106-04)</p> <ul style="list-style-type: none"> Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance <p>Drug: Ipilimumab</p> <ul style="list-style-type: none"> Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance Other Names: <ul style="list-style-type: none"> BMS-734016
<p>Experimental: C4</p> <p>BMS-936558: 3 mg/kg Ipilimumab: 10 mg/kg</p>	<p>Drug: BMS-936558 (MDX1106-04)</p> <ul style="list-style-type: none"> Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance <p>Drug: Ipilimumab</p> <ul style="list-style-type: none"> Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance Other Names: <ul style="list-style-type: none"> BMS-734016
<p>Experimental: C5</p> <p>BMS-936558: 10 mg/kg Ipilimumab: 10 mg/kg</p>	<p>Drug: BMS-936558 (MDX1106-04)</p> <ul style="list-style-type: none"> Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance

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	<p>maintenance</p> <ul style="list-style-type: none">• Other Names:<ul style="list-style-type: none">◦ BMS-734016
Experimental: C5	Drug: BMS-936558 (MDX1106-04) <ul style="list-style-type: none">• Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance Drug: Ipilimumab <ul style="list-style-type: none">• Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance• Other Names:<ul style="list-style-type: none">◦ BMS-734016

Outcome Measures

Primary Outcome Measures	1. Maximum tolerated dose [Time Frame: Completion of each dosing cohort]
Secondary Outcome Measures	1. Safety assessment based on Adverse Event reports, results of clinical laboratory tests, immune safety tests, physical exam, vital signs, ECG evaluation and ECOG [Time Frame: Safety is assessed at all study timepoints] 2. Tumor response evaluations [Time Frame: Tumor response is assessed at weeks 12, 18, 24, 30, 36, 48, 60, 72, 84, 96 and 108] 3. Pharmacokinetic peak and trough concentration of each study drug when given in combination compared to historical monotherapy data [Time Frame: PK is collected pre and post dose]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	<p>Inclusion Criteria:</p> <ul style="list-style-type: none">• Histologic diagnosis of malignant melanoma (MEL)• Measurable unresectable Stage III or IV MEL• ECOG performance status score of 0 or 1• Life expectancy $\geq$ 4 months <p>Exclusion Criteria:</p> <ul style="list-style-type: none">• History of severe hypersensitivity reactions to other mAbs• Prior malignancy active within the previous 2 years• Active autoimmune disease or a history of known or suspected autoimmune

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- ECOG performance status score of 0 or 1
- Life expectancy $\geq$ 4 months

Exclusion Criteria:

- History of severe hypersensitivity reactions to other mAbs
- Prior malignancy active within the previous 2 years
- 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
- Prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-CTLA-4 antibody
- 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 HIV, AIDS, hepatitis B, hepatitis C

Contacts/Locations

Central Contact Person	• Name	For participation information at a USA site use a phone number below. For site information outside the USA please email:
	Email	Clinical.Trials@bms.com
	• Name	First line of email MUST contain NCT# & Site#. Only trial sites that are recruiting have contact information at this time.
Study Officials	• Name	Bristol-Myers Squibb
	Role	Study Director
	Affiliation	Bristol-Myers Squibb
Location	• Los Angeles, California, United States, 90025	
	Status:	Not yet recruiting
	Facility:	Local Institution
	Contact:	◦ Contact
		▪ Site 002
	• New Haven, Connecticut, United States, 06520	
	Status:	Recruiting
	Facility:	Yale University School Of Medicine
	Contact:	◦ Contact
		▪ Mario Sznol, Site 001
	• New York, New York, United States, 10021	
	Status:	Recruiting
	Facility:	Memorial Sloan Kettering Cancer Center
	Contact:	◦ Contact
		▪ Jedd D. Wolchok, Site 003
		▪ 646-888-2395

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• New Haven, Connecticut, United States, 06520

Status: **Recruiting**

Facility: Yale University School Of Medicine

Contact:

- Contact
 - Mario Sznol, Site 001

• New York, New York, United States, 10021

Status: **Recruiting**

Facility: Memorial Sloan Kettering Cancer Center

Contact:

- Contact
 - Jedd D. Wolchok, Site 003
 - 646-888-2395

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