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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



Study Details

Researcher View

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	None (earliest version on record)
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☐	3	2010-01-04	- Study Status - Arms and Interventions
☐	4	2010-01-12	Study Status
☐	5	2010-02-03	Study Status
☐	6	2010-02-18	- Recruitment Status - Study Status - Contacts/Locations
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☐	8	2010-03-17	Study Status
☐	9	2010-03-31	Study Status
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☐	17	2010-08-11	Study Status
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☐	95	2020-06-15	Study Status Results Submission Events (4) +
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Document Section

Version 58: 2012-04-30

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	2012-04
Overall Status	Recruiting
Study Start	2009-12
Primary Completion	2013-01 [Estimated]
Study Completion	2014-02 [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	2012-04-30
Last Update Posted	2012-05-01 [Estimated]

Sponsor/Collaborators

Sponsor	Bristol-Myers Squibb
Responsible Party	Sponsor
Collaborators	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 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)
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	7
Masking	None (Open Label)
Allocation	Non-Randomized
Enrollment	96 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Arm C1 (BMS-936558: 0.3 mg/kg + Ipilimumab: 3 mg/kg)	Drug: BMS-936558 (MDX1106-04) - Solution, intravenous (IV), 0.3 mg/kg (60 min infusion), q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance Drug: Ipilimumab (BMS-734016) - Solution, IV, 3 mg/kg (90 minute infusion), q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance - Other Names: - BMS-734016
Experimental: Arm C2 (BMS-936558: 1 mg/kg + Ipilimumab: 3 mg/kg)	Drug: Ipilimumab (BMS-734016) - Solution, IV, 3 mg/kg (90 minute infusion), q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance - Other Names: - BMS-734016 Drug: BMS-936558 (MDX1106-04) - Solution, IV, 1 mg/kg (60 min infusion), q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance
Experimental: Arm C3: (BMS-936558: 3 mg/kg + Ipilimumab: 3 mg/kg)	Drug: Ipilimumab (BMS-734016) - Solution, IV, 3 mg/kg (90 minute infusion), q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance - Other Names: - BMS-734016 Drug: BMS-936558 (MDX1106-04) - Solution, IV, 3 mg/kg (60 min infusion), q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance
Experimental: Arm C4 (BMS-936558: 3 mg/kg + Ipilimumab: 10 mg/kg)	Drug: BMS-936558 (MDX1106-04) - Solution, IV, 3 mg/kg (60 min infusion), q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance Drug: Ipilimumab (BMS-734016) - Solution, IV, 10 mg/kg (90 minute infusion), q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance
Experimental: Arm C5 (BMS-936558: 10 mg/kg + Ipilimumab: 10 mg/kg)	Drug: BMS-936558 (MDX1106-04) Solution, IV, 10 mg/kg (60 min infusion), q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance

	Drug: Ipilimumab (BMS-734016) Solution, IV, 10 mg/kg (90 minute infusion), q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance
Experimental: Arm C6: (BMS-936558: 1 mg/kg)	Drug: BMS-936558 (MDX1106-04) Solution, IV, 1 mg/kg (60 min infusion), once a week for 4 weeks, and week 5 off; total maximal duration of for 96 weeks
Experimental: Arm C7: (BMS-936558: 3 mg/kg)	Drug: BMS-936558 (MDX1106-04) Solution, IV, 3 mg/kg (60 min infusion), once a week for 4 weeks, and week 5 off; total maximal duration of for 96 weeks

Outcome Measures

Primary Outcome Measures	Safety assessments will be based on adverse event reports and the results of clinical laboratory tests, immune safety tests, physical examinations, vital sign measurements, ECOG performance status, and ECG evaluations Eastern Cooperative Oncology Group (ECOG), electrocardiogram (ECG) [Time Frame: Up to 12 weeks after the last dose of the last study drug dose (approximately up to 5.5 years)]
Secondary Outcome Measures	- Pharmacokinetic peak and trough concentration of each study drug when given in combination together or in a sequenced regimen [Time Frame: Cohorts 1-5: Day 1, 2, 3, 8, 15, 22, 43, 64, 85, 106, 127, 148, 169, 253 & 6 & 12 weeks after last dose of study drug. Cohort 6-7: Day 1, 57, 113, 225, 337, 449, 561 & 6 & 12 weeks after last dose of study drug] - Blood samples to test immunogenicity [Time Frame: Cohorts 1-5: Pre-dose at weeks 0, 6, 12, 21, 24, 36, 60, 84, 108, and 12 weeks after last dose of study drug. Cohorts 6-7: Pre-dose at weeks 1, 9, 18, 36, 54, 72, 90, 108, 126, 144, 162, 180, and 12 weeks after last dose of study drug] - Tumor response evaluations [Time Frame: Cohorts 1-5: At weeks 12, 18, 24, 30, 36, 48, 60, 72, 84, 96 and 108. Cohorts 6-7: At weeks 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 108, 120, 132, 144, 156, 168, 180]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	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 $\geq$ 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 $\geq$ 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 $\geq$ 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

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

IPD Sharing

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