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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
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☐	12	2010-05-21	Study Status
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Amgen v. BMS

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Version 3: 2010-01-04

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	2010-01
Overall Status	Not yet recruiting
Study Start	2009-12
Primary Completion	2014-07 [Estimated]
Study Completion	2014-07 [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	2010-01-04
Last Update Posted	2010-01-05 [Estimated]

Sponsor/Collaborators

Sponsor	Bristol-Myers Squibb
Responsible Party	
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 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	N/A
Enrollment	46 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: C1 BMS-936558 (MDX1106-040): 0.3 mg/kg Ipilimumab: 3 mg/kg	Drug: BMS-936558 (MDX1106-04) - Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance Drug: Ipilimumab - Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance - Other Names: - BMS-734016
Experimental: C2 BMS-936558 (MDX1106-040): 0.3 mg/kg Ipilimumab: 10 mg/kg	Drug: BMS-936558 (MDX1106-04) - Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance Drug: Ipilimumab - Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance - Other Names: - BMS-734016
Experimental: C3 BMS-936558 (MDX1106-040): 1 mg/kg Ipilimumab: 10 mg/kg	Drug: BMS-936558 (MDX1106-04) - Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance Drug: Ipilimumab - Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance - Other Names: - BMS-734016
Experimental: C4 BMS-936558 (MDX1106-040): 3 mg/kg Ipilimumab: 10 mg/kg	Drug: BMS-936558 (MDX1106-04) - Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance Drug: Ipilimumab - Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance - Other Names: - BMS-734016
Experimental: C5 BMS-936558 (MDX1106-040): 10 mg/kg Ipilimumab: 10 mg/kg	Drug: BMS-936558 (MDX1106-04) - Solution, IV, 60 min infusion, q3 weeks for 21 weeks in induction and q12 weeks for 84 weeks in maintenance Drug: Ipilimumab - Solution, IV, 90 minute infusion, q3 weeks for 9 weeks in induction and q12 weeks for 84 weeks in maintenance - Other Names: - 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	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 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	- NameFor participation information at a USA site use a phone number below. For site information outside the USA please email: EmailClinical.Trials@bms.com - NameFirst line of email MUST contain NCT# & Site#. Only trial sites that are recruiting have contact information at this time.
Study Officials	- NameBristol-Myers Squibb - RoleStudy Director - AffiliationBristol-Myers Squibb
Location	Los Angeles, California, United States, 90025 Facility:Local Institution Contact: - Contact - Site 002 New Haven, Connecticut, United States, 06520 Facility:Yale University School Of Medicine Contact: - Contact - Mario Sznol, Site 001 New York, New York, United States, 10021 Facility:Memorial Sloan Kettering Cancer Center Contact: - Contact - Jedd D. Wolchok, Site 003 646-888-2395

IPD Sharing

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