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Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma (CheckMate 067)

ClinicalTrials.gov ID ⓘ NCT01844505

Sponsor ⓘ Bristol-Myers Squibb

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

Last Update Posted ⓘ 2024-01-10



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	2013-04-30	None (earliest version on record)
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☐	3	2013-08-12	- Study Status - Contacts/Locations
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☐	6	2013-09-30	- Study Status - Contacts/Locations
☐	7	2013-10-31	- Study Status - Contacts/Locations - Study Identification
☐	8	2013-11-28	- Study Status - Contacts/Locations
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☐	26	2014-11-13	Study Status
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☐	82	2017-08-28	- Study Status - Contacts/Locations - Study Design - Outcome Measures - References - Participant Flow - Baseline Characteristics - Adverse Events - More Information
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☐	94	2023-10-12	- Study Status - Contacts/Locations - References
☐	95	2023-10-24	Study Status
☐	96	2024-01-05	- Study Status - Contacts/Locations - References

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Document Section

Version 1: 2013-04-30

Study Details

Study Identification

Unique Protocol ID	CA209-067
Brief Title	Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma
Official Title	A Phase 3, Randomized, Double-Blind Study of Nivolumab Monotherapy or Nivolumab Combined With Ipilimumab Versus Ipilimumab Monotherapy in Subjects With Previously Untreated Unresectable or Metastatic Melanoma
Secondary IDs	2012-005371-13

Study Status

Record Verification	2013-04
Overall Status	Not yet recruiting
Study Start	2013-06
Primary Completion	2016-10 [Estimated]
Study Completion	2017-01 [Estimated]
First Submitted	2013-04-29
First Submitted that Met QC Criteria	2013-04-30
First Posted	2013-05-01
Last Update Submitted that Met QC Criteria	2013-04-30
Last Update Posted	2013-05-01 [Estimated]

Sponsor/Collaborators

Sponsor	Bristol-Myers Squibb
Responsible Party	Sponsor
Collaborators	

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 show that Nivolumab and/or Nivolumab in combination with Ipilimumab will extend survival compared to Ipilimumab alone
Detailed Description	CheckMate 067: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 067

Conditions

Condition	Unresectable or Metastatic Melanoma
Keywords	

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 3
Interventional Study Model	Parallel Assignment
Interventional Model Description	
Number of Arms	3
Masking	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description	
Allocation	Randomized
Enrollment	915 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Arm A: Nivolumab+Placebo for Ipilimumab+Placebo for Nivolumab Nivolumab 3 mg/kg solution intravenously every 2 weeks plus Placebo matching with Ipilimumab 0 mg/kg solution intravenously on weeks 1, 4 and Placebo matching with Nivolumab on weeks 4 for cycles 1 and 2, until documented disease progression, discontinuation due to toxicity, withdrawal of consent or the study ends	Biological: Nivolumab - Other Names: - BMS-936558 - MDX-1106 Biological: Placebo for Nivolumab Biological: Placebo for Ipilimumab
Experimental: Arm B: Nivolumab+Ipilimumab+Placebo for Nivolumab Nivolumab 1 mg/kg solution intravenously combined with Ipilimumab 3 mg/kg solution intravenously every 3 weeks for 4 doses then Nivolumab 3 mg/kg solution intravenously every 2 weeks plus Placebo matching with Nivolumab on weeks 3 and 5 for cycles 1 and 2, until documented disease progression, discontinuation due to toxicity, withdrawal of consent or the study ends	Biological: Nivolumab - Other Names: - BMS-936558 - MDX-1106 Biological: Ipilimumab - Other Names: - Yervoy - BMS-734016 - MDX-010 Biological: Placebo for Nivolumab
Experimental: Arm C: Ipilimumab+Placebo for Nivolumab Ipilimumab 3 mg/kg solution intravenously every 3 weeks for a total of 4 doses plus Placebo matching with Nivolumab 0 mg/kg solution intravenously on weeks 3 and 5 for cycles 1 and 2, until documented disease progression, discontinuation due to toxicity, withdrawal of consent or the study ends	Biological: Ipilimumab - Other Names: - Yervoy - BMS-734016 - MDX-010 Biological: Placebo for Nivolumab

Outcome Measures

Primary Outcome Measures	1. Endpoint of Overall Survival (OS) in all randomized subjects OS is defined as the time between the date of randomization and the date of death due to any cause. OS will be censored on the last date a subject was known to be alive. OS data will be collected continuously while subjects are on study medication and every 3 months via in-person or phone contact after discontinuation of study medication [Time Frame: Approximately up to 44.1 months]
Secondary Outcome Measures	1. Progression Free Survival (PFS) PFS is defined as the time between the date of randomization and the first date of documented progression, as determined by the investigator, or death due to any cause, whichever occurs first [Time Frame: Baseline (Day 1), Week 12, every 6 weeks thereafter up to week 49, and then every 12 weeks until disease progression is documented (Approximately around 5 years)] 2. Objective Response Rate (ORR) ORR is defined as the number of subjects with a Best Overall Response (BOR) of Complete Response (CR) or Partial Response (PR) divided by the number of randomized subjects for each treatment group. The BOR is defined as the best response designation, as determined by the investigator, recorded between the date of randomization and the date of objectively documented progression per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 or the date of subsequent anti-cancer therapy, whichever occurs first [Time Frame: Baseline (Day 1), Week 12 every 6 weeks thereafter up to week 49, and then every 12 weeks until disease progression is documented (expected to be no more than 5 years)] 3. Differences in OS, PFS, and ORR between the two experimental arms [Time Frame: OS: Approximately up to 44.1 months; PFS and ORR: Baseline (Day 1), Week 12, every 6 weeks thereafter up to week 49, and then every 12 weeks until disease progression is documented (Approximately around 5 years)] 4. OS based on PD-L1 expression [Time Frame: Baseline (Day 1)] 5. Mean changes from baseline in EORTC-QLQ-C30 European Organisation for Research and Treatment of Care Quality of Life Questionnaire (EORTC QLQ) C-30 global health status/QoL composite scale data and the remaining EORTC QLQ C-30 scale data will be summarized by timepoint using descriptive statistics for each treatment group [Time Frame: Day 1 of Week 1, Day 1 of Week 5 and Follow up visits 1 and 2]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	For additional information, please contact the BMS oncology clinical trial information service at 855-216-0126 or email MyCancerStudyConnect@emergingmed.com. Please visit www.BMSStudyConnect.com for more information on clinical trial participation. Inclusion Criteria: - Histologically confirmed stage III (unresectable) or stage IV melanoma - Treatment naïve patients - Measurable disease by computed tomography (CT) or Magnetic Resonance Imaging (MRI) per RECIST 1.1 criteria - Tumor tissue from an unresectable or metastatic site of disease for biomarker analyses - Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1 Exclusion Criteria: - Active brain metastases or leptomeningeal metastases - Ocular melanoma - Subjects with active, known or suspected autoimmune disease - Subjects with a condition requiring systemic treatment with either corticosteroids (>10 mg daily prednisone equivalents) or other immunosuppressive medications within 14 days of treatment - Prior treatment with an anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD-L2, or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibody

Contacts/Locations

Central Contact Person	
Study Officials	Name Bristol-Myers Squibb Role Study Director Affiliation Bristol-Myers Squibb
Location	

IPD Sharing

Available IPD/Information	
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