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COMPLETED ⓘ

A Phase 1 Study of Nivolumab (BMS-936558) in Subjects With Advanced or Recurrent Malignancies (MDX1106-03)

ClinicalTrials.gov ID ⓘ **NCT00730639**

Sponsor ⓘ Bristol-Myers Squibb

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

Last Update Posted ⓘ 2021-12-03



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	2008-08-07	None (earliest version on record)
☐	2	2008-10-23	- Recruitment Status - Study Status - Contacts/Locations - Study Description - Eligibility
☐	3	2009-02-03	- Study Status - Contacts/Locations
☐	4	2009-06-24	- Study Status - Arms and Interventions - Study Identification - Study Description - Study Design - Contacts/Locations - Outcome Measures - Eligibility - Sponsor/Collaborators
☐	5	2009-11-19	- Study Status - Contacts/Locations - Conditions - Study Identification - Outcome Measures - Arms and Interventions
☐	6	2010-03-11	- Study Status - Study Identification - Sponsor/Collaborators - Contacts/Locations
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☐	9	2010-11-10	- Recruitment Status - Study Status
☐	10	2010-11-19	- Recruitment Status - Study Status - Contacts/Locations
☐	11	2011-03-10	- Study Status - Conditions - Arms and Interventions - Eligibility - Outcome Measures
☐	12	2011-05-11	- Study Status - Conditions - Study Design
☐	13	2011-07-27	Study Status
☐	14	2011-10-19	- Study Status - Sponsor/Collaborators

Amgen Exhibit 1014
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☐	15	2012-05-22	- Recruitment Status - Study Status - Contacts/Locations - References
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☐	23	2013-07-30	- Study Status - Study Design
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☐	25	2013-09-25	Study Status
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☐	33	2014-05-02	Study Status
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☐	35	2014-05-27	Study Status
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☐	39	2014-08-11	Study Status
☐	40	2014-09-15	Study Status
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☐	44	2014-11-20	Study Status
☐	45	2014-12-05	Study Status
☐	46	2014-12-31	Study Status
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☐	59	2015-11-04	Study Status
☐	60	2016-03-24	- Study Status - Study Identification - Study Design - Outcome Measures - Eligibility - Participant Flow - Baseline Characteristics - Adverse Events - More Information
☐	61	2017-06-09	- Study Status - Oversight - References
☐	62	2017-10-19	- Study Status - Conditions - Contacts/Locations

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Document Section



Version 1: 2008-08-07

Study Details

Study Identification

Unique Protocol ID	MDX1106-03
Brief Title	A Phase 1b Study of MDX-1106 in Subjects With Advanced or Recurrent Malignancies
Official Title	A Phase 1b, Open-Label, Multicenter, Multidose, Dose-Escalation Study of MDX-1106 in Subjects With Selected Advanced or Recurrent Malignancies
Secondary IDs	

Study Status

Record Verification	2008-08
Overall Status	Not yet recruiting
Study Start	
Primary Completion	
Study Completion	
First Submitted	2008-08-04
First Submitted that Met QC Criteria	2008-08-07
First Posted	2008-08-08 [Estimated]
Last Update Submitted that Met QC Criteria	2008-08-07
Last Update Posted	2008-08-08 [Estimated]

Sponsor/Collaborators

Sponsor	Medarex
Responsible Party	
Collaborators	

Oversight

U.S. FDA-regulated Drug	
U.S. FDA-regulated Device	
Data Monitoring	No

Study Description

Brief Summary	The purpose of this study is to help determine the safety and effectiveness of MDX-1106 in patients with certain types of cancer. Another purpose is to determine how MDX-1106 is absorbed and distributed within the body, and how it's eventually eliminated.
Detailed Description	The primary objective of the study is to characterize the safety and tolerability of multiple doses of MDX-1106 in subjects with selected advanced or recurrent malignancies. The malignancies include: metastatic castration-resistant prostate cancer (mCCRPC), renal cell carcinoma (RCC), malignant melanoma (MEL), and non-small cell lung cancer (NSCLC). The secondary objectives are to: 1) assess the host immune response to MDX-1106 (immunogenicity); 2) characterize the pharmacokinetic profile of multiple doses of MDX-1106; 3) assess the efficacy of MDX-1106 monotherapy; and 4) explore the effects of MDX-1106 on humoral and cellular immune responses to tumor antigens and recall responses to a panel of non-tumor antigens.

Conditions

Condition	Metastatic Castration-Resistant Prostrate Cancer (mCRPC) Renal Cell Carcinoma (RCC) Malignant Melanoma (MEL) Non-Small Cell Lung Cancer (NSCLC)
Keywords	

Study Design

Study Type	Interventional
Primary Purpose	
Study Phase	Phase 1
Interventional Study Model	Parallel Assignment
Number of Arms	1
Masking	None (Open Label)
Allocation	
Enrollment	76 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: cohort	Biological: MDX-1106
3 cohorts, 1,3,and 10mg/kg	1, 3, or 10mg/kg MDX-1106 infusion cohort, 4 doses every 2 weeks

Outcome Measures

Primary Outcome Measures	1. To characterize the safety and tolerability of multiple doses of MDX-1106 [Time Frame: Up to 12 eight (8) week cycles, each cycle is comprised of 4 doses, on days 1,15,29,and 43]
Secondary Outcome Measures	1. Immunogenicity and PK of multiple doses [Time Frame: up to 12 eight week cycles] 2. Assess the efficacy of MDX-1106 as monotherapy [Time Frame: up to 12 eight week cycles]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: 1. Adults at least 18 years of age 2. Life expectancy of at least 12 weeks 3. Subjects must have mCRPC,RCC, MEL, or NSCLC, confirmed by available pathology records or current biopsy, that is advanced (non-resectable), or recurrent and for which no alternative, curative standard exists. 4. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2 5. Must have at least 1 measurable lesion per Response Evaluation Criteria in Solid Tumors (RECIST) with modification. The measurable lesion(s) must be outside the field of radiation therapy (RT) if there was prior treatment with RT.Subjects with mCRPC and with only non-measurable bone lesions must have either progression with 2 or more new lesions or have PSA progression within the 6-week period before study administration 6. At least 1 and up to 5 prior systemic therapies for advanced/recurrent disease (unlimited hormonal therapies allowed) 7. Prior chemotherapy or immunotherapy (tumor vaccine, cytokine, or growth factor given to control the cancer must have been completed at least 4 weeks before study drug administration, and all adverse events have either returned to baseline or stabilized 8. Prior treated brain or meningeal metastases must be without MRI evidence of progression for at least 8 weeks and off immunosuppressive doses of systemic steroids (> 10mg/day prednisone or equivalent) for at least 2 weeks before study drug administration 9. Prior systemic radiation therapy must have been completed at least 4 weeks before study drug administration. Prior focal radiotherapy completed at least 2 weeks prior to study drug administration. No radiopharmaceuticals (strontium, samarium) within 8 weeks before study drug administration 10. Immunosuppressive doses of systemic medications, such as steroids or absorbed topical steroids (doses > 10mg/day prednisone or equivalent) must be discontinued at least 2 weeks before study drug administration 11. Prior surgery that required general anesthesia must be completed at least 4 weeks before study drug administration. surgery requiring local/epidural anesthesia must be completed at least 72 hours before study drug administration and subjects should be recovered 12. Screening laboratory values must meet the following criteria: - WBC at least 2000/μL Neutrophils at least 1500/μL Platelets at least 100x10000/μL - Hemoglobin at least 9.0 g/dL - Creatinine less then or equal to 2 mg/dL - AST less then or equal to 2.5 X ULN without, and less then or equal to 5 x ULN with hepatic metastasis - ALT less then or equal to 2.5 X ULN without, and less then or equal to 5 x ULN with hepatic metastasis - Bilirubin less then or equal to 2 X ULN (except subjects with Gilbert's syndrome, who must have total bilirubin < 3.0 mg/dL)

13. Women must meet 1 of the following criteria:
- Post-menopausal for at least 24 consecutive months; surgically incapable of bearing children (i.e., have had a hysterectomy or bilateral oophorectomy); or utilizing a reliable form of contraception.
 - Women of child bearing potential must agree to use a reliable form of contraceptive during the study Treatment Period and for at least 70 days following the last dose of study drug; and
14. Men must agree to the use of male contraception during the study Treatment Period and for at least 180 days after the last dose of study drug.

Exclusion Criteria:

Subjects who fulfill any of the following criteria at Screening will not be eligible for admission into the study:

1. History of severe hypersensitivity reactions to other mAbs;
2. Prior malignancy active within the previous 2 years except for locally curable cancers that have been adequately treated, such as basal or squamous cell skin cancer, superficial bladder cancer or carcinoma in situ of the cervix or breast;
3. Subjects with any active autoimmune disease or a documented history of autoimmune disease, or history of syndrome that required systemic steroids or immunosuppressive medications, except for subjects with vitiligo or resolved childhood asthma/atopy;
4. Prior therapy with an anti-PD-1, anti-PD-L1, anti-PDL-2, or anti-CTLA-4 antibody (or any other antibody targeting T cell co-stimulation pathways);
5. Known history of Human Immunodeficiency Virus;
6. Active infection requiring therapy, positive tests for Hepatitis B surface antigen or Hepatitis C ribonucleic acid (RNA);
7. Underlying medical conditions that, in the Investigator's opinion, will make the administration of study drug hazardous or obscure the interpretation of toxicity determination or adverse events;
8. Concurrent medical condition requiring the use of immunosuppressive medications, or immunosuppressive doses of systemic or absorbable topical corticosteroids;
9. Use of other investigational drugs (drugs not marketed for any indication) within 28 days or at least 5 half-lives (whichever is longer) before study drug administration; or
10. Pregnant or nursing.

Contacts/Locations

Central Contact Person	
Study Officials	
Location	

IPD Sharing

IPD information	
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