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COMPLETED ⓘ

A Study of MDX-1106 in Patients With Selected Refractory or Relapsed Malignancies (MDX1106-01)

ClinicalTrials.gov ID ⓘ **NCT00441337**

Sponsor ⓘ Bristol-Myers Squibb

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

Last Update Posted ⓘ 2015-02-20



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	2007-02-27	None (earliest version on record)
☐	2	2007-03-27	- Study Status - Study Identification - Contacts/Locations
☐	3	2007-06-15	- Study Status - Contacts/Locations - Study Design
☐	4	2007-08-14	- Study Status - Contacts/Locations
☐	5	2007-10-22	Study Status
☐	6	2008-01-03	- Study Status - Conditions - Arms and Interventions - Outcome Measures - Sponsor/Collaborators - Study Description - Eligibility - Contacts/Locations
☐	7	2008-05-27	- Recruitment Status - Study Status
☐	8	2009-06-24	- Study Status - Sponsor/Collaborators - Study Identification - Eligibility - Study Description
☐	9	2010-02-03	- Recruitment Status - Study Status - Study Identification - Sponsor/Collaborators - Study Design - Contacts/Locations
☐	10	2010-04-22	Study Status
☐	11	2015-02-05	- Study Identification - Study Status - Sponsor/Collaborators - Study Description - Arms and Interventions - Outcome Measures - Eligibility - Participant Flow - Baseline Characteristics - Adverse Events - More Information

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Document Section



Version 1: 2007-02-27

Study Details

Study Identification

Unique Protocol ID	MDX1106-01
Brief Title	Safety and PK Study of MDX-1106 in Patients With Selected Refractory or Relapsed Malignancies
Official Title	A Phase 1, Open Label, Dose-Escalation, Safety and Pharmacokinetic Study of MDX-1106 in Patients With Selected or Relapsed Malignancies
Secondary IDs	

Study Status

Record Verification	2007-02
Overall Status	Recruiting
Study Start	2006-08
Primary Completion	
Study Completion	2009-12
First Submitted	2007-02-27
First Submitted that Met QC Criteria	2007-02-27
First Posted	2007-02-28 [Estimated]
Last Update Submitted that Met QC Criteria	2007-02-27
Last Update Posted	2007-02-28 [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	A total of 39 patients with recurrent or treatment refractory malignancies, including non-small cell lung cancer, colorectal cancer, malignant melanoma, renal clear cell cancer and hormone refractory prostate cancer, will be enrolled. Six patients will be enrolled into each of 4 dose levels of MDX-1106. An additional 10-15 patient will be enrolled at the highest dose level determined to be safe. Patients may be eligible for re-treatment provided they meet all re-treatment criteria. Patient will be followed every 2 months for tumor response until disease progression or relapse.
Detailed Description	A total of 39 patients with recurrent or treatment refractory malignancies, including non-small cell lung cancer, colorectal cancer, malignant melanoma, renal clear cell cancer and hormone refractory prostate cancer, may be enrolled. Six patients each will be enrolled at dose levels of 0.3, 1.0, 3.0 and 10mg/kg; the remaining 10 to 15 patients may subsequently be enrolled at a dose at or below the maximum tolerated dose (MTD) during the dose-escalation portion of the study. If the MTD is not reached, the additional patients will receive a dose determined by review of the available safety and efficacy data. Enrollment expansion cohort will be stopped if the incidence of dose-limiting toxicity at that dose level reaches 33%. the study will consist of 3 phases: the Single-dose Phase, the Re-treatment Phase, and the Follow-up Phase, which will include the tracking of patients for progression-free survival. Single-dose Phase: Patients in the first cohort will be observed 24 hours post dose. Patients in subsequent cohorts will have an 8 hour post dose observation period. Patients who experience any adverse events during the 8 hours will continue to be monitored for an additional 16 hours. No two patients will be enrolled on the same day. Dosing of the next higher dose level will not be initiated until all 6 patients in the previous cohort have been dosed and 5 of the 6 patients have been followed for at least 4 weeks. Clinical laboratory test samples and pharmacokinetic samples will be collected. Immunogenicity testing will be performed, and immun function assays and tumor blood tests will be performed. Re-treatment Phase: After participating in the Single-dose Phase, patients may be eligible for immediate retreatment with cycle(s) consisting of 2 additional doses of MDX-1106 (administered 4 weeks apart), provided they meet all criteria. Patients may be eligible to receive additional re-treatment cycles. Long-term Follow-up Phase: Patients who respond to therapy with a complete response or partial response will enter into the long-term follow-up phase of the protocol and may be eligible for re-treatment at the time of disease progression. Patients will be monitored every 2 months until disease progression or for 2 years, whichever comes first.

Conditions

Condition	Carcinoma, Non-Small-Cell Lung Colorectal Cancer Malignant Melanoma Renal Cancer Prostate Cancer
Keywords	malignancies cancer non small cell lung cancer lung cancer colorectal cancer adenocarcinoma melanoma malignant melanoma renal cancer renal carcinoma carcinoma prostate cancer prostate adenocarcinoma Recurrent or treatment refractory malignancies including non-small cell lung cancer, colorectal cancer, malignant melanoma, renal cancer and prostate cancer

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 1
Interventional Study Model	Single Group Assignment
Masking	None (Open Label)
Allocation	Non-Randomized
Enrollment	39

Arms and Interventions

Arms	Assigned Interventions
	Drug: MDX-1106

Outcome Measures

Primary Outcome Measures	1. vital sign measurements 2. clinical laboratory tests 3. physical examinations 4. electrocardiograms 5. incidence and severity of treatment-emergent adverse events
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Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: - Signed Informed Consent/HIPPA Authorization - Histologic diagnosis of non-small cell lung cancer, colorectal adenocarcinoma, malignant melanoma, renal (clear) cell carcinoma, or hormone-refractory prostate adenocarcinoma. Tumor must be recurrent or treatment-refractory for which no alternative, standard therapy exists. - Prior chemotherapy or immunotherapy (tumor vaccine, cytokine, or growth factor given to control the cancer) must have been completed at least 4 weeks prior to enrollment and all adverse changes have either returned to baseline or stabilized - Prior systemic radiation therapy completed at least 4 weeks prior to study drug administration. Prior focal radiotherapy completed at least 2 weeks prior to study drug administration. No radiopharmaceuticals (strontium, samarium) within 8 weeks prior to study drug administration. - Prior major treatment-related surgery completed at least 4 weeks prior to study drug administration. - No prior primary or metastatic brain or menigeal tumors unless clinically and radiographically stable as well as off steroid therapy for at least 2 months. - Life expectancy 12 weeks or greater - Age 18 years or older - Body Mass Index of 18 or greater and 30 or less - ECOG Performance Status of 0 or 1 - Use of contraception - Meet all screening laboratory values Exclusion Criteria: - History of severe hypersensitivity reactions to other monoclonal antibodies - Other prior malignancy, except for adequately treated basal or squamous cell skin cancer or superficial bladder cancer, or any other cancer from which the patient has been disease free for at least 5 years - patients 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 patients with vitiligo
- Prior therapy with an anti-PD-1 or anti-CTLA-4 antibody
 - Active infection requiring therapy, positive tests for HIV-1, HIV-2, or HTLV-1 serum antibody, hepatitis B surface antigen, or hepatitis C positive RNA
 - Underlying medical condition that, in the opinion of the Investigator, will make administration of the study drug hazardous or obscure the interpretation of toxicity determination or adverse events
 - concurrent medical condition requiring the use of immunosuppressive medications, or systemic or topical corticosteroids; systemic or topical corticosteroids must be discontinued at least 4 weeks prior to enrollment. Inhaled or intranasal corticosteroids (with minimal systemic absorption may be continued if the patient is on a stable dose). Non-absorbed intra-articular steroid injections will be permitted
 - Use of other investigational drugs within 30 days prior to study drug administration.

Contacts/Locations

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	Status:	Recruiting
	Facility:	Carolina BioOncology Institute, PLLC
	Contact:	◦ Principal Investigator ▪ John D Powderly, MD

IPD Sharing

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References

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Revision: v2.11.2