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COMPLETED ⓘ

Study of MDX-010 in Subjects With Unresectable Stage III or Stage IV Malignant Melanoma

ClinicalTrials.gov ID ⓘ **NCT00729950**

Sponsor ⓘ Bristol-Myers Squibb

Information provided by ⓘ Bristol-Myers Squibb

Last Update Posted ⓘ 2010-04-26



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Study Details

Researcher View

No 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	2010-02-03	- Study Status - Study Identification - Sponsor/Collaborators - Contacts/Locations
☐	3	2010-04-23	Study Status

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On this page

Study Record Versions

[Study Details](#)

[Study Identification](#)

[Study Status](#)

[Sponsor/Collaborators](#)

[Oversight](#)

[Study Description](#)

[Conditions](#)

[Study Design](#)

[Arms and Interventions](#)

[Outcome Measures](#)

[Eligibility](#)

[Contacts/Locations](#)

[IPD Sharing](#)

[References](#)

[Document Section](#)



Version 1: 2008-08-07

Study Details

Study Identification

Unique Protocol ID	MDX010-15
Brief Title	Study of MDX-010 in Subjects With Unresectable Stage III or Stage IV Malignant Melanoma
Official Title	An Open-Label Pharmacokinetic and Safety Study of MDX-010 in Subjects With Unresectable Stage III or Stage IV Malignant Melanoma
Secondary IDs	

Study Status

Record Verification	2008-08
Overall Status	Completed
Study Start	2003-07
Primary Completion	2005-10 [Actual]
Study Completion	2007-06 [Actual]
First Submitted	2008-08-06
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	This is a Phase I, open-label, multicenter, pharmacokinetic study of MDX-010 in up to 90 evaluable subjects with surgically unresectable malignant melanoma.
Detailed Description	Group A: Six to 12 subjects will be treated with transfectoma-derived MDX-010 at 2.8 or 5 mg/kg/dose, or with hybridoma-derived MDX-010 at 3 mg/kg/dose administered on Days 1, 57, and 85. The 2.8, 3, and 5 mg/kg dosage cohorts may be initiated concurrently. Additionally, 6 subjects per cohort will receive single doses of transfectoma-derived MDX-010 at 7.5, 10, 15, and 20 mg/kg. Dose escalation from the 5 mg/kg cohort to the 7.5 mg/kg cohort will depend on the safety profile following a single dose of 5 mg/kg. Once all subjects are enrolled in the 5 mg/kg cohort and 4 weeks have elapsed since the sixth subject in the cohort has received the first infusion, dose escalation to the 7.5 mg/kg cohort may occur if ≤ 1 DLT has occurred in the 5 mg/kg cohort. Dose escalation to the 10 mg/kg cohort may occur 4 weeks after the sixth subject in the 7.5 mg/kg/dose cohort has received the first infusion (with ≤ 1 DLT). Dose escalation to the 15 and 20 mg/kg cohorts may occur 4 weeks after the sixth subject in the previous cohort has received the first infusion (with ≤ 1 DLT). Up to six additional subjects may be enrolled in the MTD dose cohort or in the 20 mg/kg dose cohort if MTD is not attained. Group B: If single-dose administration of MDX-010 at 10 mg/kg is well tolerated (≤ 1 DLT in the cohort in Group A), then an additional 12 to 20 subjects will be enrolled and treated with MDX-010 at 10 mg/kg/dose administered on Days 1, 22, 43, and 64. Subjects who respond to therapy will be followed until disease progression or a maximum of approximately 1 year. Subjects with a response of SD $\geq$ 3 months, PR, or CR to their initial treatment cycle who subsequently relapse may be eligible for retreatment with the same regimen or an alternate regimen considered to be more effective at the time of retreatment.

Conditions

Condition	Malignant Melanoma
Keywords	

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	92 [Actual]

Arms and Interventions

Arms	Assigned Interventions
	Biological: MDX-010 Subjects will be treated with transfectoma-derived MDX-010 at 2.8 or 5 mg/kg/dose, or with hybridoma-derived MDX-010 at 3 mg/kg/dose administered on Days 1, 57, and 85. The 2.8, 3, and 5 mg/kg dosage cohorts may be initiated concurrently. Additionally, 6 subjects per cohort will receive single doses of transfectoma-derived MDX-010 at 7.5, 10, 15, and 20 mg/kg.

Outcome Measures

Primary Outcome Measures	1. To determine the safety and pharmacokinetic profile of single and multiple doses of MDX-010. [Time Frame: up to approximately 1 year]
Secondary Outcome Measures	1. Determine the clinical activity profile of single and multiple doses of MDX-010 [Time Frame: up to approximately one year.]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: • Subject must have read, understood, and provided written informed consent and authorization in compliance with the Health Insurance Portability and Accountability Act (HIPAA) after the nature of the study has been fully explained. • Subject must be at least 18 years of age with a histologic diagnosis of unresectable Stage III or IV malignant melanoma (may include mucosal melanoma). Subjects with either stable or progressive malignancy will be permitted in the study. Classification of stable or progressive disease, to be recorded for all subjects, will be defined by the Response Evaluation Criteria in Solid Tumors (RECIST), as detailed in Appendix 3 and determined since last melanoma treatment. Subjects must have at least 1 site of measurable disease. • At least 4 weeks since treatment (surgery, chemotherapy, radiation, or immuno-therapy) for melanoma and recovered from any serious toxicity experienced during treatment. • Life expectancy of at least 18 weeks. • Karnofsky Performance Status of at least 70% • Screening laboratory values must meet the following criteria: ◦ WBC ≥2500/μL ◦ ANC ≥1500/μL ◦ Platelets ≥100 x 10³/μL ◦ Hematocrit ≥30% ◦ Hemoglobin ≥10 g/dL ◦ Creatinine ≤2 mg/dL ◦ AST ≤2 x ULN* ◦ Bilirubin ≤1.0 x ULN*, (except subjects with Gilbert's Syndrome, who must have a total bilirubin less than 3.0 mg/dL.) ◦ HIV negative ◦ HBsAg negative ◦ anti-HCV nonreactive. If reactive, subject must have a negative HCV RNA qualitative PCR. ◦ Unless definitely attributable to disease. Exclusion Criteria: • Any prior malignancy except for the following: adequately treated basal or squamous cell skin cancer, superficial bladder cancer, carcinoma in situ of the cervix, or any other cancer from which the subject has been disease-free for at least 5 years • History of autoimmune disease (including uveitis and autoimmune inflammatory eye disease) prior to entrance into the study. • Active infection requiring therapy, chronic active HBV or HCV, or confirmed reactivity with HIV tests. • Tetanus booster immunization within 2 months of initial screening procedures, or a history of anaphylaxis or severe local reaction to the tetanus vaccine. • Pregnant or nursing; it is not known what effect MDX-010 could have on the developing immune system of the fetus or infant, therefore, exposure in utero or via breast milk will not be allowed. • Any underlying medical condition which, in the opinion of the principal investigator, will make the administration of study drug hazardous or obscure the interpretation of adverse events. • Any concurrent medical condition requiring the use of systemic or topical corticosteroids or the use of immunosuppressive agents (e.g. cyclosporine and its analog, or chemotherapy agents). All corticosteroid use must have been discontinued at least 4 weeks prior to trial entry. • Prior treatment with MDX-010 or any other anti-CTLA-4 monoclonal antibody. • Evidence or history of significant cardiac, pulmonary, hepatic, renal, psychiatric or gastrointestinal disease that would make the administration of MDX-010 unsafe. • Concurrent treatment with chemotherapy or other immunotherapy regimens (must be completed at least 4 weeks before Screening).

Contacts/Locations

Central Contact Person	
Study Officials	• Name: Michael Yellin, MD - Role: Study Director - Affiliation: Medarex
Location	• Tucson, Arizona, United States, 85724-5024 Facility: Arizona Cancer Center • Los Angeles, California, United States, 90033 Facility: USC/Norris Comprehensive Cancer Center • Charlotte, North Carolina, United States, 28207 Facility: Piedmont Oncology Specialists • Portland, Oregon, United States, 97213 Facility: Providence Portland Medical Center

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