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COMPLETED ⓘ

MDX-010 Antibody, MDX-1379 Melanoma Vaccine, or MDX-010/MDX-1379 Combination Treatment for Patients With Unresectable or Metastatic Melanoma

ClinicalTrials.gov ID ⓘ **NCT00094653**

Sponsor ⓘ Bristol-Myers Squibb

Information provided by ⓘ Bristol-Myers Squibb

Last Update Posted ⓘ 2011-07-11



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	2005-06-26	None (earliest version on record)
☐	2	2005-07-21	- Study Status - Contacts/Locations
☐	3	2005-08-22	- Study Status - Contacts/Locations
☐	4	2005-08-24	- Study Status - Contacts/Locations
☐	5	2005-08-29	- Study Status - Contacts/Locations
☐	6	2005-09-13	- Study Status - Contacts/Locations
☐	7	2005-10-05	- Study Status - Contacts/Locations
☐	8	2005-10-19	- Study Status - Contacts/Locations
☐	9	2005-10-28	- Study Status - Study Identification - Contacts/Locations
☐	10	2005-11-04	- Study Status - Contacts/Locations
☐	11	2005-11-07	- Study Status - Contacts/Locations
☐	12	2005-11-21	- Study Status - Contacts/Locations
☐	13	2005-11-22	- Study Status - Contacts/Locations
☐	14	2005-12-16	- Study Status - Contacts/Locations
☐	15	2006-01-10	- Study Status - Contacts/Locations
☐	16	2006-01-18	- Study Status - Contacts/Locations
☐	17	2006-01-30	- Study Status - Contacts/Locations
☐	18	2006-03-08	- Study Status - Contacts/Locations
☐	19	2006-03-28	- Study Status - Contacts/Locations
☐	20	2006-04-06	- Study Status - Contacts/Locations
☐	21	2006-04-20	- Study Status - Contacts/Locations
☐	22	2006-05-04	- Study Status - Contacts/Locations

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☐	23	2006-06-21	• Study Status • Contacts/Locations
☐	24	2006-08-25	• Study Status • Contacts/Locations
☐	25	2006-10-13	• Study Status • Contacts/Locations
☐	26	2006-10-27	• Study Status • Contacts/Locations
☐	27	2006-11-03	• Study Status
☐	28	2006-11-09	• Study Status • Contacts/Locations
☐	29	2006-11-28	• Study Status • Contacts/Locations
☐	30	2007-07-09	• Study Status • Contacts/Locations • Study Design
☐	31	2007-08-06	• Study Status • Contacts/Locations
☐	32	2007-09-12	• Study Status • Contacts/Locations
☐	33	2007-12-05	• Study Status • Study Design • Arms and Interventions • Contacts/Locations • Outcome Measures • Sponsor/Collaborators
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☐	45	2010-02-26	• Study Status • Contacts/Locations • Outcome Measures
☐	46	2010-03-11	• Study Status • Study Identification • Sponsor/Collaborators • Contacts/Locations
☐	47	2010-04-23	• Study Status
☐	48	2010-09-10	• Study Status
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Version 1: 2005-06-26

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Document Section

Study Details

Study Identification

Unique Protocol ID	MDX010-20
Brief Title	MDX-010 Antibody, MDX-1379 Melanoma Vaccine, or MDX-010/MDX-1379 Combination Treatment for Patients with Melanoma
Official Title	A Randomized, Double-Blind, Multicenter Study Comparing MDX-010 Monotherapy, MDX-010 in Combination with a Melanoma Peptide Vaccine, and Melanoma Vaccine Monotherapy in HLA-A2*0201-Positive Patients with Previously Treated Unresectable Stage III or IV Melanoma
Secondary IDs	

Study Status

Record Verification	2005-06
Overall Status	Recruiting
Study Start	2004-09
Primary Completion	
Study Completion	
First Submitted	2004-10-21
First Submitted that Met QC Criteria	2004-10-21
First Posted	2004-10-22 [Estimated]
Certification/Extension First Submitted	2010-09-10
Last Update Submitted that Met QC Criteria	2005-06-26
Last Update Posted	2005-06-24 [Estimated]

Sponsor/Collaborators

Sponsor	Medarex
Responsible Party	
Collaborators	

Oversight

U.S. FDA-regulated Drug	
U.S. FDA-regulated Device	
Data Monitoring	

Study Description

Brief Summary	The purpose of this study is to determine the safety and efficacy of MDX-010 (anti-CTLA4) in combination with MDX-1379 in patients with previously treated, unresectable Stage III or IV melanoma. Survival time will be evaluated, as well as patient responses and time to disease progression. Eligible patients are those who in response to a single regimen containing IL-2, dacarbazine, and/or temozolomide, have 1) relapsed following an objective response (PR/CR); 2) failed to demonstrate an objective response (PR/CR); or 3) could not tolerate such a regimen due to unacceptable toxicity. Patients will be randomized into one of three groups, and will receive one of the following treatments: MDX-010 alone, MDX-1379 alone, or MDX-010 in combination with MDX-1379.
Detailed Description	Melanoma accounts for approximately 5% of all skin cancers in the United States, but it accounts for about 75% of all skin cancer deaths. In 2004, the expected prevalence of melanoma is 627,252, with about 119,178 of these cases being Stage III or IV (metastatic melanoma). First line treatments for metastatic melanoma, usually IL-2, dacarbazine and/or temozolomide, are associated with significant toxicities. MDX-010 (anti-CTLA4) antibodies are designed to keep the immune system running by blocking CTLA-4 from down-regulating T cell activation. MDX-1379 is made up of two peptides that are pieces of a bigger melanoma protein (gp100). These peptides bind to HLA-A2 which is then recognized by T cells.

Conditions

Condition	Melanoma Metastases
Keywords	melanoma metastatic melanoma skin cancer

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 3
Interventional Study Model	
Masking	Double
Allocation	Randomized
Enrollment	750

Arms and Interventions

Arms	Assigned Interventions
	Drug: MDX-010 (anti-CTLA4) monoclonal antibody Biological: MDX-1379 Melanoma Peptide Vaccine

Outcome Measures

Primary Outcome Measures	1. Best Objective Response Rate
Secondary Outcome Measures	1. Overall Survival 2. Major durable response rate 3. duration of response 4. progression free survival 5. time to progression

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: • Diagnosed with malignant melanoma • Measurable unresectable Stage III or IV melanoma • At least 18 years old • HLA-A*0201 positive • Previous treatment with & failure/relapse/inability to tolerate IL-2, dacarbazine and/or temozolomide • At least 4 weeks since prior treatment • Negative pregnancy • Life expectancy greater than 4 months • ECOG performance of 0 or 1 • Required lab values • HIV, HBV, HCV negative Exclusion Criteria: • Prior malignancies which the patient has not been disease free for 5 years, except treated and cured basal or squamous cell skin cancer, superficial bladder cancer, carcinoma in situ of the cervix, or any other cancer • Ocular melanoma • Active, untreated CNS metastasis • Prior treatment with MDX-010 (anti-CTLA4) antibody • Prior treatment with any cancer therapeutic vaccine • Active autoimmune disease or history of autoimmune disease • Pregnancy or nursing • Hypersensitivity to Incomplete Freund's Adjuvant (IFA) (Montanide ISA-51) • Underlying medical conditions deemed hazardous if treated with study drug • Concomitant therapy with anti-melanoma drugs, chemotherapies, other investigational therapies, chronic use of systemic corticosteroids • Unable to provide informed consent

Contacts/Locations

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