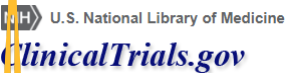


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Trial record 1 of 1 for: NCT00729664

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Multiple Ascending Dose (MDX1105-01) (Anti-PDL1)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT00729664

Recruitment Status : Completed
First Posted : August 7, 2008
Last Update Posted : September 7, 2015

[View this study on Beta.ClinicalTrials.gov](#)

Sponsor:
Bristol-Myers Squibb

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

Study Details Tabular View No Results Posted Disclaimer ? How to Read a Study Record

Study Description

Go to

Brief Summary:
Collection of survival data, evaluation of PDL-1 expression in tumors, and evaluation of PD-L1 receptor occupancy in peripheral blood has been added.

Condition or disease	Intervention/treatment	Phase
Cancer, Multiple Indications	Biological: Anti-PDL-1 antibody	Phase 1

Detailed Description:
This is an open label, multicenter, dose escalation and multidose study of MDX-11-5, a fully human monoclonal IgG4 antibody targeting the Programed Death-Ligand 1 (PD-L1).
The study will consist of 3 periods: Screening (up to 28 days), Treatment (up to 16 six-week cycles), and Follow-up (up to 6 months).

Study Design

Go to

Study Type : Interventional (Clinical Trial)
Actual Enrollment : 281 participants
Allocation: Non-Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Treatment
Official Title: A Phase 1, Multidose Study of BMS-936559 (MDX-1105) Administered Every 14 Days in Subjects With Selected Advanced or Recurrent Solid Tumors
Study Start Date : February 2009
Actual Primary Completion Date : July 2015
Actual Study Completion Date : July 2015

Arms and Interventions

Go to

Arm	Intervention/treatment
-----	------------------------

Arm 	Intervention/treatment 
Experimental: Anti-PDL-1 antibody (Arm 1) BMS-936559 (MDX-1105)	Biological: Anti-PDL-1 antibody Solution, Intravenous, 0.1 mg/kg, Every 14 days, 3 doses per each cycle of 42 days, 16 cycles/48 doses depending on response Other Names: - BMS-936559 - MDX 1105
Experimental: Anti-PDL-1 antibody (Arm 2) BMS-936559 (MDX-1105)	Biological: Anti-PDL-1 antibody Solution, Intravenous, 0.3 mg/kg, Every 14 days, 3 doses per each cycle of 42 days, 16 cycles/48 doses depending on response Other Names: - BMS-936559 - MDX 1105
Experimental: Anti-PDL-1 antibody (Arm 3) BMS-936559 (MDX-1105)	Biological: Anti-PDL-1 antibody Solution, Intravenous, 1 mg/kg, Every 14 days, 3 doses per each cycle of 42 days, 16 cycles/48 doses depending on response Other Names: - BMS-936559 - MDX 1105
Experimental: Anti-PDL-1 antibody (Arm 4) BMS-936559 (MDX-1105)	Biological: Anti-PDL-1 antibody Solution, Intravenous, 3 mg/kg, Every 14 days, 3 doses per each cycle of 42 days, 16 cycles/48 doses depending on response Other Names: - BMS-936559 - MDX 1105
Experimental: Anti-PDL-1 antibody (Arm 5) BMS-936559 (MDX-1105)	Biological: Anti-PDL-1 antibody Solution, Intravenous, 10 mg/kg, Every 14 days, 3 doses per each cycle of 42 days, 16 cycles/48 doses depending on response Other Names: - BMS-936559 - MDX 1105

Outcome Measures

Go to Primary Outcome Measures

1. Safety, maximum tolerated dose (MTD) and dose-limiting toxicity(DLT)of MDX-1105 [Time Frame: Weekly]
2. Safety, maximum tolerated dose (MTD) and dose-limiting toxicity(DLT)of MDX-1105 [Time Frame: Bi-weekly]

Secondary Outcome Measures

1. Preliminary efficacy in solid tumors on the basis of objective responses [Time Frame: Day 42]

Eligibility Criteria

Go to 

Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
 Sexes Eligible for Study: All
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 to 1
- The malignancies include relapsed/refractory renal cell carcinoma, non-small cell lung cancer, colorectal adenocarcinoma, malignant melanoma, advanced/metastatic epithelial ovarian cancer, gastric cancer, pancreatic cancer and breast cancer
- Must have measurable disease

Exclusion Criteria:

- Prior therapy with an anti-PD 1, anti-PDL 1, or anti-Cytotoxic T-Lymphocyte Antigen 4 antibody (or any other agents that target T-cell co-stimulation)

Contacts and Locations

Go to 

Information from the National Library of Medicine



To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT00729664**

Locations

United States, California

The Angeles Clinic & Research Institute
Los Angeles, California, United States, 90025

United States, Georgia

Emory University
Atlanta, Georgia, United States, 30322

United States, Illinois

University Of Chicago
Chicago, Illinois, United States, 60637

United States, Maryland

Johns Hopkins University
Baltimore, Maryland, United States, 21231

United States, Minnesota

Mayo Clinic
Rochester, Minnesota, United States, 55905

United States, New York

Roswell Park Cancer Institute
Buffalo, New York, United States, 14263

United States, Ohio

University Of Cincinnati
Cincinnati, Ohio, United States, 45267
Ohio State University
Columbus, Ohio, United States, 43210

United States, Texas

Oncology Consultants, Pa
Houston, Texas, United States, 77024
The University Of Texas
Houston, Texas, United States, 77030

United States, Washington

Fred Hutchinson Cancer Center
Seattle, Washington, United States, 98109

Sponsors and Collaborators

Bristol-Myers Squibb

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

Go to 

Additional Information:

[BMS clinical trial educational resource](#) 

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

[Brahmer JR, Tykodi SS, Chow LQ, Hwu WJ, Topalian SL, Hwu P, Drake CG, Camacho LH, Kauh J, Odunsi K, Pitot HC, Hamid O, Bhatia S, Martins R, Eaton K, Chen S, Salay TM, Alaparthi S, Grosso JF, Korman AJ, Parker SM, Agrawal S, Goldberg SM, Pardoll DM, Gupta A, Wigginton JM. Safety and activity of anti-PD-L1 antibody in patients with advanced cancer. N Engl J Med. 2012 Jun 28;366\(26\):2455-65. doi: 10.1056/NEJMoa1200694. Epub 2012 Jun 2.](#)

Responsible Party: Bristol-Myers Squibb
ClinicalTrials.gov Identifier: [NCT00729664](#) [History of Changes](#)
Other Study ID Numbers: CA210-001
MDX1105-01 (Other Identifier: BMS)
First Posted: August 7, 2008 [Key Record Dates](#)
Last Update Posted: September 7, 2015
Last Verified: September 2015

Additional relevant MeSH terms:

Atezolizumab	Immunologic Factors
BMS-936559	Physiological Effects of Drugs
Antibodies	Antineoplastic Agents
Immunoglobulins	Antineoplastic Agents, Immunological
Antibodies, Monoclonal	