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| | Trial re | ecord 1 of 1 for: NCT00729664 | |
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| Multiple | Ascending Dose (MDX1105-01) (Anti-PDL1) | | |
| A | e safety and scientific validity of this study is the responsibility of t leral Government. Read our <u>disclaimer</u> for details. | he study sponsor and investigators. Listing a study doe | es not mean it has been evaluated by the U.S. |
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| 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

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 💌 |
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| | | | |
| Information from the National Library of Medicine | | | |
| Choosing to participate in a study is a | n important personal decision. Talk with your doctor and family members or fi | riends about deciding to join a study. To | |
| learn more about this study, you or yo | our doctor may contact the study research staff using the contacts provided be | elow. For general information, <u>Learn</u> | |
| About Clinical Studies. | | | |
| | | | |
| Ages Eligible for Study: | 18 Years and older (Adult, Older Adult) | | |
| Sexes Eligible for Study: | All | | |
| Accepts Healthy Volunteers: | No | | |
| Criteria | | | |
| | | Dana- | Farber EX1045 |
| os://clinicaltrials.gov/ct2/show/NC | CT00729664?term=NCT00729664&draw=2&rank=1 | Dana-Farber v. BMS, I | |

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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 breastcancer

• 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

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

Additional Information:

BMS clinical trial educational resource

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

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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, Alaparthy 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: ClinicalTrials.gov Identifier: Other Study ID Numbers:

First Posted: Last Update Posted: Last Verified:

Additional relevant MeSH terms: Atezolizumab

BMS-936559 Antibodies Immunoglobulins Antibodies, Monoclonal Bristol-Myers Squibb <u>NCT00729664</u><u>History of Changes</u> CA210-001 MDX1105-01 (Other Identifier: BMS) August 7, 2008<u>Key Record Dates</u> September 7, 2015 September 2015

> Immunologic Factors Physiological Effects of Drugs Antineoplastic Agents Antineoplastic Agents, Immunological