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An Investigational Immuno-therapy Study to Assess the Safety, Tolerability and Effectiveness of Anti-LAG-3 With and Without Anti-PD-1 in the Treatment of Solid Tumors

ClinicalTrials.gov ID ⓘ **NCT01968109**

Sponsor ⓘ Bristol-Myers Squibb

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

Last Update Posted ⓘ 2024-06-20



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.

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Study Record Versions

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Study Identification

Version 1: 2013-10-18

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Document Section

Study Details

Study Identification

Unique Protocol ID	CA224-020
Brief Title	Safety Study of Anti-LAG-3 With and Without Anti-PD-1 in the Treatment of Solid Tumors
Official Title	A Phase 1 Dose Escalation and Cohort Expansion Study of the Safety, Tolerability, and Efficacy of Anti-LAG-3 Monoclonal Antibody (BMS-986016) Administered Alone and in Combination With Anti-PD-1 Monoclonal Antibody (Nivolumab, BMS-936558) in Advanced Solid Tumors
Secondary IDs	

Study Status

Record Verification	2013-10
Overall Status	Not yet recruiting
Study Start	2013-12
Primary Completion	2016-09 [Estimated]
Study Completion	2020-10 [Estimated]
First Submitted	2013-09-25
First Submitted that Met QC Criteria	2013-10-18
First Posted	2013-10-23 [Estimated]
Last Update Submitted that Met QC Criteria	2013-10-18
Last Update Posted	2013-10-23 [Estimated]

Sponsor/Collaborators

Sponsor	Bristol-Myers Squibb
Responsible Party	Sponsor
Collaborators	

Oversight

U.S. FDA-regulated Drug	
U.S. FDA-regulated Device	
Data Monitoring	No

Study Description

Brief Summary	To assess the safety and tolerability, characterize the dose-limiting toxicities, and identify the maximum tolerated dose of BMS-986016 alone and in combination with Nivolumab in subjects with select advanced (metastatic and/or unresectable) solid tumors and to provide preliminary information on the clinical benefits of the combination.
Detailed Description	

Conditions

Condition	Neoplasms by Site
Keywords	

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 1
Interventional Study Model	Parallel Assignment
Number of Arms	3
Masking	None (Open Label)
Allocation	Non-Randomized
Enrollment	168 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Part A-Dose Escalation: BMS-986016 BMS-986016 20, 80, 240, and 800 mg solution intravenously, during each 8 week cycle: every 2 weeks (i.e. during weeks 1, 3, 5, 7), up to 96 weeks	Biological: BMS-986016 - Other Names: - Anti-LAG-3 (Anti-Lymphocyte Activation Gene-3)
Experimental: Part B-Dose Escalation: BMS-986016 + BMS-936558 BMS-986016 3, 20, 80, and 240 mg solution + BMS-936558 80 and 240 mg solution intravenously, during each 8 week cycle: every 2 weeks (i.e. during weeks 1, 3, 5, 7), up to 96 weeks	Biological: BMS-986016 - Other Names: - Anti-LAG-3 (Anti-Lymphocyte Activation Gene-3) Biological: BMS-936558 - Other Names: - Anti-PD-1 (Anti-Programmed-Death-1) - MDS-1106 - Nivolumab
Experimental: Part C-Cohort Expansion: BMS-986016 + BMS-936558 BMS-986016 + BMS-936558 at doses selected in Part B, during each 8 week cycle: every 2 weeks (i.e. during weeks 1, 3, 5, 7), up to 96 weeks	Biological: BMS-986016 - Other Names: - Anti-LAG-3 (Anti-Lymphocyte Activation Gene-3) Biological: BMS-936558 - Other Names: - Anti-PD-1 (Anti-Programmed-Death-1) - MDS-1106 - Nivolumab

Outcome Measures

Primary Outcome Measures	Safety as measured by the rate of AEs, serious AEs, deaths and laboratory abnormalities (e.g. Grade 3 or higher per CTCAE v4) CTCAE = Common Terminology Criteria for Adverse Events (AEs); AEs = Adverse events; SAEs = Serious adverse events [Time Frame: Approximately Up to 2.3 years (96 weeks of treatment period and 135 days of follow-up)]
Secondary Outcome Measures	- Maximum observed serum concentration (Cmax) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Time of maximum observed serum concentration (Tmax) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Trough observed serum concentration (Ctrough) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 14 time points up to Cycle 12 (approximately 96 weeks)] - Concentration at the end of a dosing interval (Ctau) [Eg: concentration at 336 hours] of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 14 time points up to Cycle 12 (approximately 96 weeks)] - Average concentration over a dosing interval [AUC(TAU)/tau] (Css,avg) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Area under the concentration-time curve in one dosing interval [AUC(TAU)] of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Total body clearance (CLT) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Volume of distribution at steady state (Vss) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Effective elimination half-life that explains the degree of AUC accumulation observed (T-HALFeff AUC) of BMS-986016 administered both alone and in combination with nivolumab AUC = area under the concentration-time curve [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Effective elimination half-life that explains the degree of Cmax accumulation observed (T-HALFeff Cmax) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Accumulation index; ratio of AUC(TAU) at steady state to AUC(TAU) after the first dose (AL_AUC) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Cmax accumulation index; ratio of Cmax at steady state to Cmax after the first dose (AL_Cmax) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Ctau accumulation index; ratio of Ctau at steady state to Ctau after the first dose (AL_Ctau) of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 2 time points up through part of Cycle 3 (approximately 18 weeks)] - DF - Degree of fluctuation or fluctuation index [(Cmax - Ctau)/Css,avg] of BMS-986016 administered both alone and in combination with nivolumab [Time Frame: 15 time points up through part of Cycle 3 (approximately 18 weeks)] - Efficacy as measured by tumor assessment (irRECIST and RECIST) Based on Immune-related Response Evaluation Criteria for Solid Tumors (irRECIST) 1.1 and Response Evaluation Criteria In Solid Tumors (RECIST) 1.1 using Best overall response (BOR), Objective response rate (ORR), Duration of response (DOR) and Progression-free survival (PFS) [Time Frame: Every 8 weeks during treatment period (up to twelve 8-week cycles), and once during clinical follow-up period (30 days), for a total of approximately 1.9 years] - Immunogenicity measured by ADA for BMS-986016 (all subjects) and nivolumab (Part B & C only) [Time Frame: 17 time points Cycle 1 through 12, up to 135 days of follow-up] - QTc interval from centrally read electrocardiograms (ECGs) (Parts A and B) [Time Frame: Follow-up visit 1, and Day 1 of Cycles 1 and 3 (pre-dose and 4 hour post-dose time points)]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	For additional information, please contact the BMS oncology clinical trial information service at 855-216-0126 or email MyCancerStudyConnect@emergingmed.com. Please visit www.BMSStudyConnect.com for more information on clinical trial participation. Inclusion Criteria: - Part A, Dose Escalation: Advanced (metastatic and/or unresectable) and incurable solid tumors - Part B, Dose Escalation: Advanced (metastatic and/or unresectable) and incurable solid tumors, with or without most recent therapy being anti-PD-1 or anti-programmed cell death protein ligand 1 (anti-PD-L1). Subjects with anti-PD-1 or anti-PDL-1 therapy must have been unresponsive and progressed within 16 weeks of starting therapy - Part C Cohort Expansion: Advanced (metastatic and/or unresectable) and incurable melanoma (with or without the last therapy being anti-PD-1 or anti-PD-L1); non-small cell lung cancer (NSCLC) (with or without the last therapy being anti-PD-1 or anti-PD-L1) (melanoma and NSCLC subjects with anti-PD-1 or anti-PDL-1 therapy must have been unresponsive and progressed within 16 weeks of starting therapy); human papilloma virus (HPV) positive head and neck squamous cell carcinomas; or gastric adenocarcinoma - Part A: Progressed, or been intolerant to, at least one standard treatment regimen in the advanced or metastatic setting (if such a therapy exists) - Part B or C: Progressed, or been intolerant to, at least one standard treatment regimen or refuse standard treatment in the advanced or metastatic setting (if such therapy exists) - Received less than 5 prior treatment regimens - Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 - At least 1 lesion with measurable disease at baseline - Availability of an existing tumor biopsy sample (or consent to allow pre-treatment tumor biopsy if sample not available) Exclusion Criteria: - Primary central nervous system (CNS) tumors or solid tumors with CNS metastases as the only site of active disease - Uncontrolled CNS metastases - Any prior exposure to immune cell modulating antibody regimens except as described in inclusion criteria for Part B subjects or specific Part C subjects - Autoimmune disease - Encephalitis, meningitis, or uncontrolled seizures in the year prior to informed consent

Contacts/Locations

Central Contact Person	
Study Officials	- NameBristol-Myers Squibb - RoleStudy Director - AffiliationBristol-Myers Squibb
Location	

IPD Sharing

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