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ACTIVE, NOT RECRUITING ⓘ

A Study of Nivolumab Alone or Nivolumab Combination Therapy in Colon Cancer That Has Come Back or Has Spread (CheckMate142)

ClinicalTrials.gov ID ⓘ **NCT02060188**

Sponsor ⓘ Bristol-Myers Squibb

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

Last Update Posted ⓘ 2024-08-09



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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☐	3	2014-03-28	- Study Status - Contacts/Locations
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Version 1: 2014-02-10

Study Details

Study Identification

Unique Protocol ID	CA209-142
Brief Title	A Study of Nivolumab and Nivolumab Plus Ipilimumab in Recurrent and Metastatic Colon Cancer (CheckMate 142)
Official Title	A Phase 2 Clinical Trial of Nivolumab and Nivolumab Plus Ipilimumab in Recurrent and Metastatic Microsatellite High (MSI-H) Colon Cancer
Secondary IDs	2013-003939-30

Study Status

Record Verification	2014-02
Overall Status	Not yet recruiting
Study Start	2014-02
Primary Completion	2016-12 [Estimated]
Study Completion	2017-07 [Estimated]
First Submitted	2013-12-18
First Submitted that Met QC Criteria	2014-02-10
First Posted	2014-02-11 [Estimated]
Last Update Submitted that Met QC Criteria	2014-02-10
Last Update Posted	2014-02-11 [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	The purpose of this study is to examine if Nivolumab alone or in combination with Ipilimumab will demonstrate a meaningful objective response rate in patients with recurrent and metastatic colon cancer who also have a specific biomarker in their tumors
Detailed Description	Allocation: The Microsatellite Instability High (MSI-High) Part of the trial is Non-randomized, The Non-MSI high part of the trial contains a randomized portion

Conditions

Condition	MSI Positive Colorectal Cancer MSI Negative Colorectal Cancer
Keywords	

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 1 Phase 2
Interventional Study Model	Parallel Assignment
Number of Arms	2
Masking	None (Open Label)
Allocation	Non-Randomized
Enrollment	96 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Nivolumab Monotherapy	Drug: Nivolumab - Other Names: - BMS-936558
Nivolumab administered as IV infusion at a dose of 3mg/kg every 2 weeks until disease progression	
Experimental: Nivolumab + Ipilimumab	Drug: Ipilimumab
Dose Escalation Phase:	Drug: Nivolumab - Other Names: - BMS-936558
Dose Level -1: Nivolumab 0.3mg/Kg IV combined with Ipilimumab 1 mg/Kg IV every 3 weeks for 4 doses followed by Nivolumab 3mg/Kg IV every 2 weeks until disease progression	
Dose Level 1: Nivolumab 1mg/Kg IV combined with Ipilimumab 1 mg/Kg IV every 3 weeks for 4 doses followed by Nivolumab 3mg/Kg IV every 2 weeks until disease progression	
Dose Level 2a: Nivolumab 1mg/Kg IV combined with Ipilimumab 3 mg/Kg IV every 3 weeks for 4 doses followed by Nivolumab 3mg/Kg IV every 2 weeks until disease progression	
Dose Level 2b: Nivolumab 3mg/Kg IV combined with Ipilimumab 1 mg/Kg IV every 3 weeks for 4 doses followed by Nivolumab 3mg/Kg IV every 2 weeks until disease progression	

Outcome Measures

Primary Outcome Measures	1. Objective response rate (ORR) in all MSI-High subjects as determined by Investigators (Tumor imaging assessments will occur every 6 weeks from the date of first dose (+/- 1 wk) for the first 24 weeks, then every 12 wks (+/- 1 wk) thereafter until disease progression or treatment is discontinued (whichever occurs later)) (Tumor imaging assessments will occur every 6 weeks from the date of first dose (+/- 1 wk) for the first 24 weeks, then every 12 wks (+/- 1 wk) thereafter until disease progression or treatment is discontinued (whichever occurs later)) [Time Frame: The final analysis of the primary endpoint will occur at least 6 months after the last enrolled subject's first dose of study therapy (Approximately up to 34 months)]
Secondary Outcome Measures	1. ORR in all MSI-H subjects based on IRRC determination Tumor imaging assessments will occur every 6 weeks from the date of first dose (+/- wk) for the first 24 weeks, then every 12 wks (+/- 1 wk) thereafter until disease progression or treatment is discontinued(whichever occurs later) [Time Frame: The final analysis of the secondary endpoint will occur the time of the primary endpoint analysis (Approximately up to 34 months)]

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	For more information regarding BMS clinical trial participation, please visit www.BMSStudyConnect.com Inclusion Criteria: - Men and women ≥ 18 years of age - Eastern Cooperative Oncology Group (ECOG) performance status 0 to 1 - Histologically confirmed colorectal cancer - Measurable disease by CT or MRI - Testing for MSI Status - Adequate organ function as defined by study-specific laboratory tests - Must use acceptable form of birth control throughout the study. After the final dose of study drug, an acceptable form of birth control must be used for 23 weeks for women of childbearing potential (WOCBP) and 31 weeks for men who are sexually active with WOCBP - Signed informed consent - Willing and able to comply with study procedures Exclusion Criteria: - Active brain metastases or leptomeningeal metastases are not allowed. - Prior treatment with an anti-Programmed Death Receptor (PD)-1, anti-PD-L1, anti-PD-L2, anti-Cytotoxic T-Cell Lymphoma-4 Antigen (CTLA-4) antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways - Prior malignancy active within the previous 3 years except for locally curable cancers - Subjects with active, known or suspected autoimmune disease - Subjects with a condition requiring systemic treatment with either corticosteroids or other immunosuppressive medications within 14 days of study drug administration

Contacts/Locations

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

IPD Sharing

IPD information

References

Citations

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