Study of BMS-986315 Alone and in Combination With Nivolumab or Cetuximab in Participants With Advanced Solid Tumors

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT04349267	RECRUITING	APRIL 16, 2020	JUNE 24, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to evaluate BMS-986315 alone and in combination with nivolumab or cetuximab in participants with advanced solid tumors.

Condition or Disease: Advanced Solid Tumor

Intervention/treatment: Biological: BMS-986315
Biological: nivolumab
Biological: cetuximab

Phase: Phase 1/Phase 2

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 308 participants

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: Study of BMS-986315 Alone and in Combination With Nivolumab or Cetuximab in Participants With Advanced Solid Tumors

Actual Study Start Date: July 2020

Estimated Primary Completion Date: April 2024

Estimated Study Completion Date: May 2025

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: BMS-986315	Biological: BMS-986315 Specified dose on specified days
Experimental: BMS-986315 + cetuximab	Biological: BMS-986315 Specified dose on specified days Biological: cetuximab Specified dose on specified days
Experimental: BMS-986315 + nivolumab	Biological: BMS-986315 Specified dose on specified days Biological: nivolumab Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Incidence of adverse events (AEs) [Time Frame: Up to 119 weeks]
2. Incidence of serious adverse events (SAEs) [Time Frame: Up to 119 weeks]
3. Incidence of adverse events (AEs) meeting protocol-defined DLT (dose-limiting toxicity) criteria [Time Frame: Up to 119 weeks]
4. Incidence of adverse events (AEs) leading to discontinuation [Time Frame: Up to 119 weeks]
5. Number of deaths [Time Frame: Up to 119 weeks]

Secondary Outcome Measures:
1. Objective Response Rate (ORR) [Time Frame: Up to 12 months]
2. Duration of Response (DOR) [Time Frame: Up to 12 months]
3. Progression-Free Survival Rate (PFSR) [Time Frame: Up to 12 months]
4. Maximum observed serum concentration (Cmax) of BMS-986315 [Time Frame: Up to 16 weeks]
5. Maximum observed serum concentration (Cmax) of BMS-986315 with nivolumab [Time Frame: Up to 16 weeks]
6. Maximum observed serum concentration (Cmax) of BMS-986315 with cetuximab [Time Frame: Up to 16 weeks]
7. Time of maximum observed serum concentration (Tmax) of BMS-986315 [Time Frame: Up to 16 weeks]
8. Time of maximum observed serum concentration (Tmax) of BMS-986315 with nivolumab [Time Frame: Up to 16 weeks]
9. Time of maximum observed serum concentration (Tmax) of BMS-986315 with cetuximab [Time Frame: Up to 16 weeks]
10. Area under the serum concentration-time curve from time zero to time of last quantifiable concentration (AUC(0-T)) of BMS-986315 [Time Frame: Up to 16 weeks]
11. Area under the serum concentration-time curve from time zero to time of last quantifiable concentration (AUC(0-T)) of BMS-986315 with nivolumab [Time Frame: Up to 16 weeks]

12. Area under the serum concentration-time curve from time zero to time of last quantifiable concentration (AUC(0-T)) of BMS-986315 with cetuximab [Time Frame: Up to 16 weeks]
13. Area under the serum concentration-time curve in 1 dosing interval [AUC(TAU)] of BMS-986315 [Time Frame: Up to 16 weeks]
14. Area under the serum concentration-time curve in 1 dosing interval [AUC(TAU)] of BMS-986315 with nivolumab [Time Frame: Up to 16 weeks]
15. Area under the serum concentration-time curve in 1 dosing interval [AUC(TAU)] of BMS-986315 with cetuximab [Time Frame: Up to 16 weeks]
16. Observed serum concentration at the end of a dosing interval (Ctau) of BMS-986315 [Time Frame: Up to 16 weeks]
17. Observed serum concentration at the end of a dosing interval (Ctau) of BMS-986315 with nivolumab [Time Frame: Up to 16 weeks]
18. Observed serum concentration at the end of a dosing interval (Ctau) of BMS-986315 with cetuximab [Time Frame: Up to 16 weeks]
19. Trough observed serum concentrations (Ctrough) of BMS-986315 [Time Frame: Up to 119 weeks]
20. Incidence of anti-drug antibodies to BMS-986315 [Time Frame: Up to 119 weeks]
21. Incidence of anti-drug antibodies to BMS-986315 with nivolumab [Time Frame: Up to 119 weeks]
22. Incidence of anti-drug antibodies to BMS-986315 with cetuximab [Time Frame: Up to 119 weeks]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
Participants must have histologic confirmation of advanced (metastatic, recurrent, and/or unresectable) squamous cell carcinoma of the head and neck (SCCHN), nonsmall cell lung cancer (NSCLC), or renal cell cancer (RCC) with measurable disease per RECIST 1.1 Participants expected to have received standard of care therapies including an available PD-(L)1 inhibitor Eastern cooperative oncology group performance status of 0 or 1 Women of childbearing potential must agree to follow methods of contraception
Exclusion Criteria:
Participants with active, known or suspected autoimmune disease Participants with a condition requiring systemic treatment with either corticosteroids or other immunosuppressive medications Uncontrolled or significant cardiovascular disease History of or with active interstitial lung disease or pulmonary fibrosis Prior participation in anti-natural killer cell receptor (anti-NKG2A) clinical study History of allergy or hypersensitivity to study drug components
Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: BMS Study Connect Contact Center www.BMSStudyConnect.com 855-907-3286 Clinical.Trials@bms.com
Contact: First line of the email MUST contain NCT # and Site #.

Locations

United States, Maryland	Local Institution	Baltimore
United States, South Dakota	Sanford Clinic Clinical Research	Sioux Falls
United States, Tennessee	The West Clinic, P.C.	Germantown
Argentina, Distrito Federal	Local Institution	Capital Federal
Canada, British Columbia	Local Institution - 0011	Vancouver
Canada, British Columbia	Local Institution	Vancouver
Canada, Ontario	Local Institution	Ottawa
Canada, Ontario	Local Institution	Toronto
Canada, Quebec	Local Institution	Montreal
Canada	Local Institution - 0014	Edmonton
Canada	Local Institution - 0013	Ottawa
Chile, Metropolitana	Local Institution	Recoleta
Mexico, Distrito Federal	Local Institution	Mexico city
Mexico, Nuevo LEON	Local Institution	Monterrey
Mexico	Local Institution	San Luis Potosi

Sponsors and Collaborators

Bristol-Myers Squibb

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

Responsible Party :	Bristol-Myers Squibb
ClinicalTrials.gov Identifier :	NCT04349267
Other Study ID Numbers :	CA047-004
First Posted :	April 16, 2020
Last Update Posted :	June 24, 2022
Last Verified :	June 2022
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Bristol-Myers Squibb:	*NSCLC (Non-small cell lung cancer)* *RCC (Renal cell carcinoma) SCCHN (Squamous cell carcinoma of the head and neck)*
Additional relevant MeSH terms :	*Neoplasms*