An Investigational Immunotherapy Study of BMS-986288 Alone and in Combination With Nivolumab in Advanced Solid Cancers

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03994601	RECRUITING	JUNE 21, 2019	NOVEMBER 23, 2021

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to determine whether BMS-986288 both by itself and in combination with Nivolumab is safe and tolerable in the treatment of select advanced solid tumors.

Condition or Disease: Advanced Cancer

Intervention/treatment: Drug: BMS-986288
Drug: Nivolumab

Phase: Phase 1/Phase 2

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 344 participants

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Phase 1/2 First-in-human Study of BMS-986288 Alone and in Combination With Nivolumab in Advanced Malignant Tumors

Actual Study Start Date: September 2019

Estimated Primary Completion Date: September 2023

Estimated Study Completion Date: April 2024

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Arm A BMS-986288	Drug: BMS-986288 Specified dose on specified days
Experimental: Arm B BMS-986288 in combination with Nivolumab	Drug: BMS-986288 Specified dose on specified days Drug: Nivolumab Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Incidence of Adverse Events (AEs) [Time Frame: Up to 2 years]
2. Incidence of Serious Adverse Events (SAEs) [Time Frame: Up to 2 years]
3. Incidence of AEs meeting protocol-defined Dose Limiting Toxicities (DLT) criteria [Time Frame: Up to 2 years]
4. Incidence of AEs leading to discontinuation [Time Frame: Up to 2 years]
5. Incidence of AEs leading to death [Time Frame: Up to 2 years]
6. Incidence of AEs leading to laboratory abnormalities [Time Frame: Up to 2 years]

Secondary Outcome Measures:
1. Maximum Observed Concentration (Cmax) of BMS-986288 [Time Frame: Up to 2 years]
2. Time of Maximum Observed Concentration (Tmax) of BMS-986288 [Time Frame: Up to 2 years]
3. Area Under the Concentration-Time Curve From Time Zero to Time of Last Quantifiable Concentration AUC(0-T) of BMS-986288 [Time Frame: Up to 2 years]
4. Area Under the Concentration-Time Curve in one Dosing Interval AUC(TAU) of BMS-986288 [Time Frame: Up to 2 years]
5. Observed Concentration at the end of a Dosing Interval (Ctau) of BMS-986288 [Time Frame: Up to 2 years]
6. Trough Observed Concentrations (Ctrough) of BMS-986288 [Time Frame: Up to 2 years]
7. Total Body Clearance (CLT) of BMS-986288 [Time Frame: Up to 4 months]
8. Average Concentration Over a Dosing Interval at Steady State (Cavgss) of BMS-986288 [Time Frame: Up to 4 months]
9. Accumulation Index (AI) of BMS-986288 [Time Frame: Up to 4 months]
10. Terminal Half-Life (T-HALF) of BMS-986288 [Time Frame: Up to 4 months]
11. Incidence of Anti-Drug Antibodies (ADAs) to BMS-986288 [Time Frame: Up to 2 years]
12. Objective Response Rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 by Investigator assessment [Time Frame: Up to 4 years]
13. Duration of Response (DOR) by RECIST v1.1 by Investigator Assessment [Time Frame: Up to 4 years]
14. Progression-Free Survival (PFS) by RECIST v1.1 by Investigator Assessment [Time Frame: Up to 4 years]
15. Time to Response (TTR) by RECIST v1.1 by Investigator Assessment [Time Frame: Up to 4 years]
16. Percentage of change from baseline in T-regulatory cells (Tregs) [Time Frame: Up to 2 years]

ELIGIBILITY CRITERIA

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

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

For more information regarding Bristol-Myers Squibb Clinical Trial participation, please visit www.BMSStudyConnect.com
Inclusion Criteria:
Histologic or cytologic confirmation of select solid tumor that is advanced (metastatic, recurrent, and/or unresectable) with measurable disease and have at least 1 lesion accessible for biopsy Eastern Cooperative Oncology Group Performance Status of 0 or 1 Received, and then progressed, relapsed, or been intolerant to, at least 1 standard treatment regimen in the advanced or metastatic setting according to select solid tumor histologies
Exclusion Criteria:
Active, known or suspected autoimmune disease Active malignancy requiring concurrent intervention Primary Central Nervous System (CNS) malignancies or tumors with CNS metastasis as the only site of disease, will be excluded
Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email: Clinical.Trials@bms.com
Contact: First line of the email MUST contain NCT # and Site #.

Locations

United States, Colorado	University Of Colorado	Aurora
United States, Maryland	Johns Hopkins University	Baltimore
United States, Missouri	Washington University	Saint Louis
United States, New Jersey	Hackensack University Medical Center	Hackensack
Argentina, Buenos Aires	Local Institution	Caba
Argentina, Buenos Aires	Local Institution	Ciudad Autónoma De Buenos Aires
Argentina, Cordoba	Local Institution	Río Cuarto
Argentina, Distrito Federal	Local Institution	ABB
Argentina, Distrito Federal	Local Institution	Buenos Aires
Argentina, Distrito Federal	Local Institution	Capital
Argentina	Local Institution	Cordoba
Canada, Ontario	Local Institution	Toronto
Chile, Metropolitana	Local Institution	Recoleta
Chile, Metropolitana	Local Institution	Santiago
Chile, Valparaiso	Local Institution	Viña del Mar
France	Local Institution	Bron
France	Local Institution	Lyon
France	Local Institution	Marseille
France	Local Institution	Paris
Italy	Local Institution	Ancona
Italy	Local Institution	Milano
Italy	Local Institution	Milano
Italy	Local Institution	Monza
Spain	Local Institution	Madrid
Spain	Local Institution	Majadahonda
Spain	Local Institution	Valencia

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 :	NCT03994601
Other Study ID Numbers :	CA043-001
First Posted :	June 21, 2019
Last Update Posted :	November 23, 2021
Last Verified :	November 2021
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No