A Study of BMS-986406 as Monotherapy and Combination Therapies in Participants With Advanced Tumors

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT05298592	RECRUITING	MARCH 28, 2022	JUNE 30, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to assess the safety and tolerability of BMS-986406 administered alone and in combination with nivolumab in participants with advanced tumors.

Condition or Disease: Advanced Cancer

Intervention/treatment: Biological: BMS-986406
Biological: Nivolumab

Phase: Phase 1

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 112 participants

Allocation : Non-Randomized

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Study of BMS-986406 as Monotherapy and Combination Therapies in Participants With Advanced Tumors

Actual Study Start Date: March 2022

Estimated Primary Completion Date: April 2026

Estimated Study Completion Date: July 2026

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Part 1A: BMS-986406 (Monotherapy Dose Escalation)	Biological: BMS-986406 Specified dose on specified days
Experimental: Part 1B: BMS-986406 + Nivolumab (Combination Dose Escalation)	Biological: BMS-986406 Specified dose on specified days Biological: Nivolumab Specified dose on specified days
Experimental: Part 1C: BMS-986406 + Nivolumab (Indication-Specific Dose Expansion)	Biological: BMS-986406 Specified dose on specified days Biological: Nivolumab Specified dose on specified days
Experimental: Part 2: BMS-986406 + Nivolumab (Expansion Cohorts)	Biological: BMS-986406 Specified dose on specified days Biological: Nivolumab Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Number of participants with adverse events (AEs) [Time Frame: Up to 100 days]
2. Number of participants with serious adverse events (SAEs) [Time Frame: Up to 100 days]
3. Number of participants with AEs meeting protocol defined dose-limiting toxicity (DLT) criteria [Time Frame: Up to 28 days]
4. Number of participants with AEs leading to discontinuation [Time Frame: Up to 100 days]
5. Number of participants with death [Time Frame: Up to 100 days]

Secondary Outcome Measures:
1. Maximum observed plasma concentration (Cmax) [Time Frame: Up to 14 days]
2. Time of maximum observed plasma concentration (Tmax) [Time Frame: Up to 14 days]
3. Trough observed plasma concentration (Ctrough) [Time Frame: Up to 14 days]
4. Incidence of anti-drug antibody (ADAs) [Time Frame: Up to 14 days]
5. Objective response rate (ORR) [Time Frame: Up to 24 months]

6. Disease control rate (DCR) [Time Frame: Up to 24 months]
7. Duration of response (DOR) per tumor appropriate criteria: Modified Response Evaluation Criteria in Solid Tumors (mRECIST) for mesothelioma [Time Frame: Up to 24 months]
8. DOR per tumor appropriate criteria: Prostate Cancer Working Group 3 (PCWG3) for prostate cancer [Time Frame: Up to 24 months]
9. DOR per tumor appropriate criteria: Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) for other solid tumor types [Time Frame: Up to 24 months]

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:
Histologically or cytologically confirmed locally advanced unresectable, metastatic, or recurrent malignant tumor. Eligible tumor types are non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC), pancreatic ductal adenocarcinoma (PDAC), gastric/gastroesophageal junction, castration-resistant prostate cancer (CRPC), ovarian, squamous cell carcinoma of the head and neck (SCCHN), bladder, melanoma, mesothelioma, triple negative breast cancer (TNBC), and soft tissue sarcoma, except for participants with tumors with central nervous system (CNS) metastases as the only site of active disease Measurable disease by Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1), Prostate Cancer Working Group 3 (PCWG3) (for prostate cancer), or modified Response Evaluation Criteria in Solid tumors (mRECIST) (for mesothelioma) Eastern Cooperative Oncology Group Performance Status of 0 or 1 Adequate organ function
Exclusion Criteria:
Prior organ or tissue allograft Leptomeningeal metastases Untreated CNS metastases Serious or uncontrolled medical disorders
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 email MUST contain NCT # and Site #.

Locations

United States, California	Local Institution	Los Angeles
United States, New Jersey	Hackensack University Medical Center	Hackensack
United States, North Carolina	Carolina Biooncology Institute, Pllc	Huntersville
United States, Pennsylvania	Fox Chase Cancer Center	Philadelphia
United States, Texas	Local Institution	Dallas
United States, Virginia	Local Institution	Richmond
Spain	Local Institution	Barcelona
Spain	Local Institution	Malaga

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 : NCT05298592

Other Study ID Numbers : CA111-001, 2021-006872-17, U1111-1270-3670

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Studies a U.S. FDA-regulated Drug Product: Yes

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Bristol-Myers Squibb: *Opdivo® Immunotherapy*