A Study to Evaluate Nivolumab in Combination With Ipilimumab Versus Pemetrexed With Cisplatin or Carboplatin for Unresectable Pleural Mesothelioma in Chinese Participants

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT05136677	RECRUITING	NOVEMBER 29, 2021	JUNE 14, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to assess the efficacy and safety of the combination of nivolumab and ipilimumab in Chinese participants with malignant pleural mesothelioma.

Condition or Disease: Mesothelioma, Malignant

Intervention/treatment: Biological: Nivolumab
Biological: Ipilimumab
Drug: Pemetrexed
Drug: Cisplatin
Drug: Carboplatin

Phase: Phase 2

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 100 participants

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Study to Evaluate Nivolumab in Combination With Ipilimumab Versus Pemetrexed With Cisplatin or Carboplatin for Unresectable Pleural Mesothelioma in Chinese Participants

Actual Study Start Date: January 2022

Estimated Primary Completion Date: October 2026

Estimated Study Completion Date: October 2026

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Arm A	Biological: Nivolumab Specified dose on specified days Biological: Ipilimumab Specified dose on specified days
Experimental: Arm B	Drug: Pemetrexed Specified dose on specified days Drug: Cisplatin Specified dose on specified days Drug: Carboplatin Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures: 1. Overall Survival (OS) [Time Frame: Up to 58 months]

Secondary Outcome Measures:
1. Objective Response Rate (ORR) by modified Response Evaluation Criteria in Solid Tumors (m-RECIST) by Investigator [Time Frame: Up to 58 months]
2. Progression Free Survival (PFS) by m-RECIST by Investigator [Time Frame: Up to 58 months]
3. Incidence of Adverse Events (AEs) [Time Frame: Up to 58 months]
4. Incidence of Serious Adverse Events (SAEs) [Time Frame: Up to 58 months]
5. Incidence of immune-related AEs [Time Frame: Up to 58 months]
6. Incidence of deaths [Time Frame: Up to 58 months]
7. Incidence of participants with laboratory abnormalities [Time Frame: Up to 58 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 proven diagnosis of Malignant Pleural Mesothelioma (MPM) with determination of epithelioid vs non-epithelioid histology Must have advanced unresectable disease that is not amenable to therapy with curative intent (surgery with or without chemotherapy) Available tumor samples for centralized testing Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1 Measurable disease
Exclusion Criteria:
Primitive peritoneal, pericardial, testis or tunica vaginalis mesothelioma Brain metastasis, except if surgically resected or treated with stereotaxic radiotherapy Prior therapy for MPM (including chemotherapy, radical pleuropneumonectomy and non-palliative radiotherapy)
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

China, Beijing	Local Institution - 0009	Beijing
China, Heilongjiang	Local Institution - 0013	Harbin
China, Henan	Local Institution - 0006	Zhengzhou
China, Hunan	Local Institution	Changsha
China, Hunan	Local Institution - 0005	Changsha
China, Jiangsu	Local Institution - 0015	Yangzhou
China, Jilin	Local Institution - 0003	Changchun
China, Liaoning	Local Institution	Shenyang
China, Liaoning	Local Institution - 0004	Shenyang
China, Liaoning	Local Institution - 0021	Shenyang
China, Shanghai	Local Institution	Shanghai
China, Tianjin	Local Institution - 0007	Tianjin
China, Tianjin	Local Institution - 0018	Tianjin
China, Yunnan	Local Institution	Kunming
China, Zhejiang	Local Institution	Hangzhou
China, Zhejiang	Local Institution	Hangzhou
China, Zhejiang	Local Institution - 0020	Hangzhou
China, Zhejiang	Local Institution	Ningbo
China, Zhejiang	Local Institution	Ningbo

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 : NCT05136677

Other Study ID Numbers : CA209-6DW, U1111-1265-3913

First Posted : November 29, 2021

Last Update Posted : June 14, 2022

Last Verified : June 2022

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Product Manufactured in and Exported from the U.S.:	Yes
Keywords provided by Bristol-Myers Squibb:	*Malignant Pleural Mesothelioma (MPM)* *Nivolumab Ipilimumab*

Additional relevant MeSH terms :

- *Mesothelioma*
- *Mesothelioma, Malignant*
- *Adenoma*
- *Neoplasms, Glandular and Epithelial*
- *Neoplasms by Histologic Type*
- *Neoplasms*
- *Neoplasms, Mesothelial*
- *Lung Neoplasms*
- *Respiratory Tract Neoplasms*
- *Thoracic Neoplasms*
- *Neoplasms by Site*
- *Pleural Neoplasms*
- *Lung Diseases*
- *Respiratory Tract Diseases*