A Study of BMS-986012 in Combination With Carboplatin, Etoposide, and Nivolumab as First-line Therapy in Extensive-stage Small Cell Lung Cancer

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT04702880	RECRUITING	JANUARY 11, 2021	JULY 12, 2021

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to demonstrate that treatment with BMS-986012 in combination with carboplatin, etoposide, and nivolumab will have acceptable safety and tolerability and will improve progression-free survival compared with carboplatin, etoposide, and nivolumab alone in newly diagnosed participants with extensive-stage small cell lung cancer (ES-SCLC).

Condition or Disease: Extensive-stage Small Cell Lung Cancer

Intervention/treatment: Biological: BMS-986012
Drug: Carboplatin
Drug: Etoposide
Biological: Nivolumab

Phase: Phase 2

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 120 participants

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Randomized, Open-label Phase 2 Clinical Trial of BMS-986012 in Combination With Carboplatin, Etoposide, and Nivolumab as First-line Therapy in Extensive-stage Small Cell Lung Cancer

Actual Study Start Date: March 2021

Estimated Primary Completion Date: September 2023

Estimated Study Completion Date: September 2024

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Arm A: Carboplatin + Etoposide + Nivolumab + BMS-986012	Biological: BMS-986012 Specified dose on specified days Drug: Carboplatin Specified dose on specified days Drug: Etoposide Specified dose on specified days Biological: Nivolumab Specified dose on specified days
Experimental: Arm B: Carboplatin + Etoposide + Nivolumab	Drug: Carboplatin Specified dose on specified days Drug: Etoposide 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 2 years and 100 days]
2. Incidence of serious adverse events (SAEs) [Time Frame: Up to 2 years and 128 days]
3. Incidence of AEs leading to discontinuation [Time Frame: Up to 2 years and 128 days]
4. Incidence of deaths [Time Frame: Up to 2 years and 128 days]
5. Progression-free survival (PFS) by blinded independent central review (BICR) based on Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 criteria [Time Frame: Up to 2 years]

Secondary Outcome Measures:
1. Progression-free survival rate (PFSR) [Time Frame: 6 and 12 months]
PFS by BICR based on RECIST v1.1 criteria
2. PFS by investigator based on RECIST v1.1 criteria [Time Frame: Up to 2 years]

3. PFSR [Time Frame: 6 and 12 months]
PFS by investigator based on RECIST v1.1 criteria
4. Objective response rate (ORR) based on RECIST v1.1 criteria [Time Frame: Up to 2 years]
5. Time to response (TTR) based on RECIST v1.1 criteria [Time Frame: Up to 2 years]
6. Duration of response (DOR) based on RECIST v1.1 criteria [Time Frame: Up to 2 years]
7. Overall survival (OS) [Time Frame: Up to 3 years]
By arm
8. Overall survival rate (OSR) [Time Frame: Up to 3 years]
By arm
9. Measures of tumor fucosyl-GM1 (fuc-GM1) expression by immunohistochemistry (IHC) [Time Frame: Up to 2 years]
10. Measures of tumor fucosyl-GM1 (fuc-GM1) expression association with measures of anti-tumor activity measures (eg, ORR, PFS) (IHC) [Time Frame: Up to 2 years]
11. Measures of tumor fucosyl-GM1 (fuc-GM1) expression by targeted mass spectrometry [Time Frame: Up to 2 years]
12. Measures of tumor fucosyl-GM1 (fuc-GM1) expression association with measures of anti-tumor activity measures (eg, ORR, PFS) (targeted mass spectrometry) [Time Frame: Up to 2 years]
13. Measures of tumor programmed cell death-ligand 1 (PD-L1) expression combined positive score (CPS) at baseline [Time Frame: Up to 2 years]
14. Measures of tumor programmed cell death-ligand 1 (PD-L1) expression association with measures of anti-tumor activity (eg, ORR, PFS) [Time Frame: Up to 2 years]
15. Immunogenicity of BMS-986012 measured by assessment of the presence of specific anti-drug antibodies (ADAs) to BMS-986012 (i.e. incidence of positive ADAs) [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:
Histologically or cytologically documented extensive-stage small cell lung cancer (ES-SCLC) and extensive-stage disease (American Joint Committee on Cancer, 7th edition, Stage IV [T any, N any, M1a, or M1b], or T3-4 due to multiple lung nodules that are too extensive or tumor or nodal volume that is too large to be encompassed in a tolerable radiation plan) Must provide a fresh tumor biopsy from the primary disease site (when possible) or from any metastatic site when the primary site is not available Eastern Cooperative Oncology Group performance status (ECOG PS) 0 or 1 At least 1 measurable lesion by computed tomography (CT) or magnetic resonance imaging (MRI) per Response Evaluation Criteria in Solid Tumors version 1.1 (Response Evaluation Criteria in Solid Tumors (RECIST) v1.1) criteria Adequate hematologic and end organ function Must agree to follow specific methods of contraception, if applicable
Exclusion Criteria:
Women who are pregnant or breastfeeding Prior chemotherapy, radiation therapy, or biologic therapy for small cell lung cancer (SCLC) for first-line treatment Symptomatic brain or other central nervous system (CNS) metastases Paraneoplastic autoimmune syndrome requiring systemic treatment History of idiopathic pulmonary fibrosis, drug-induced pneumonitis, idiopathic pneumonitis, organizing pneumonia, or evidence of active pneumonitis on screening chest CT scan Grade ≥ 2 peripheral sensory neuropathy at study entry Significant uncontrolled cardiovascular disease Active, known or suspected autoimmune disease or inflammatory disorder
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, Kentucky	Local Institution	Lexington
United States, New Jersey	John Theurer Cancer Center	Hackensack
United States, North Carolina	Local Institution	Durham
United States, Ohio	Local Institution	Cincinnati
United States, Texas	Local Institution	Dallas
Australia, New South Wales	Westmead Hospital-Department of Medical Oncology	Westmead
Australia, Victoria	Local Institution	Melbourne
Australia, Western Australia	St. John of God Murdoch Hospital-Medical Oncology	Murdoch
Australia	Gallipoli Medical Research Foundation-GMRF CTU	Queensland
Belgium	Local Institution	Charleroi
Belgium	Local Institution	Gent
Belgium	Local Institution	Liège
Canada, Alberta	Local Institution	Edmonton
Canada, Ontario	Local Institution	Brampton

Greece	Local Institution	Athens
Greece	Local Institution	Athens
Greece	Local Institution	Irakleio
Italy	Local Institution	Peschiera Del Garda
Italy	Local Institution	Pisa
Italy	Local Institution	Rozzano
Japan, Osaka	Local Institution	Takatsuki
Netherlands	Local Institution	Amsterdam
Netherlands	Local Institution	Arnhem
Netherlands	Local Institution	Groningen
Netherlands	Local Institution	Nijmegen
Poland	Local Institution	Gdansk
Poland	Instytut Centrum Zdrowia Matki Polki-Klinika Onkologii	Lodz
Romania	Local Institution	Bucharest
Romania	Local Institution	Cluj-Napoca
Romania	Local Institution	Craiova
Spain	Local Institution	Barcelona
Spain	Local Institution	Madrid
Spain	Local Institution	Majadahonda
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 :	NCT04702880
Other Study ID Numbers :	CA001-050, 2020-001863-10, U1111-1250-4427
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Last Verified :	July 2021
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Bristol-Myers Squibb:	*BMS-986012* *Carboplatin* *Etoposide* *Extensive-stage small cell lung cancer Fucosyl* *Nivolumab* *Targeted SCLC therapy*
Additional relevant MeSH terms :	*Lung Neoplasms* — *Neoplasms* *Small Cell Lung Carcinoma* — *Lung Diseases* *Respiratory Tract Neoplasms* — *Respiratory Tract Diseases* *Thoracic Neoplasms* — *Carcinoma, Bronchogenic* *Neoplasms by Site* — *Bronchial Neoplasms*