ClinicalTrials.gov

A Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Participants With Extensive Stage Small Cell Lung Cancer (MERU) (MERU)

This study is currently recruiting participants. (see Contacts and Locations)

Verified May 2017 by AbbVie

Sponsor:
AbbVie

Information provided by (Responsible Party):
AbbVie

ClinicalTrials.gov Identifier:
NCT03033511

First received: January 25, 2017
Last updated: May 31, 2017
Last verified: May 2017
History of Changes

Purpose

This is a Phase 3, randomized, double-blind, placebo-controlled, multinational, and multicenter study to evaluate the efficacy of rovalpituzumab tesirine as maintenance therapy following first-line platinum-based chemotherapy.

Condition	Intervention	Phase
Small Cell Lung Cancer (SCLC)	Drug: Rovalpituzumab tesirine Drug: Dexamethasone Drug: Placebo for rovalpituzumab tesirine Drug: Placebo for dexamethasone	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Participant, Care Provider, Investigator, Outcomes Assessor
Primary Purpose: Treatment

Official Title: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects With Extensive Stage Small Cell Lung Cancer (**MERU**)

Resource links provided by NLM:

Genetics Home Reference related topics: lung cancer

MedlinePlus related topics: Lung Cancer

U.S. FDA Resources

Further study details as provided by AbbVie:

Primary Outcome Measures:

- Progression-free survival (PFS) determined by a Central Radiographic Assessment Committee (CRAC) [Time Frame: Approximately 24 months since the first subject enrolled]

  PFS is defined as the number of months from randomization to disease progression, as assessed by the CRAC per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, or death of any cause, whichever occurs first.

- Overall survival (OS) [Time Frame: Approximately 31 months since first subject enrolled]

OS is defined as the number of months from randomization to death of any cause.

Secondary Outcome Measures:

- Objective response rate (ORR) per the CRAC based on RECIST v1.1 [Time Frame: Approximately 31 months since first subject enrolled]

  ORR the percentage of participants whose best overall response is either complete response (CR) or partial response (PR) per CRAC according to RECIST version 1.1 from the date of randomization until disease progression or death, whichever occurs first.

- Change in patient reported outcomes (PROs)--physical functioning domain [Time Frame: Approximately 31 months since first subject enrolled]

  EORTC QLQ-C30 is a 30-item subject self-report questionnaire composed of both multi-item and single scales, including global health status/quality of life, functional scales (physical, role, emotional, cognitive, and social), symptom scales (fatigue, nausea and vomiting, and pain), and 6 single items (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). Lung Cancer Module (QLQ-LC13) is a supplementary lung cancer-specific questionnaire to be used in conjunction with the EORTC QLQ-C30

- Progression-free survival (PFS) per investigator assessment based on RECIST v1.1 [Time Frame: Approximately 24 months since the first subject enrolled]

  PFS is defined as the number of months from randomization to disease progression, as assessed by the investigator per RECIST version 1.1, or death of any cause, whichever occurs first.

- ORR per investigator assessment based on RECIST v1.1 [Time Frame: Approximately 31 months since first subject enrolled]

  ORR is the percentage of participants whose best overall response is either complete response (CR) or partial response (PR) per investigator assessment according to RECIST version 1.1 from the date of randomization until disease progression or death, whichever occurs first.

- Clinical benefit rate (CBR) per the CRAC assessment based on RECIST v1.1 [Time Frame: Approximately 31 months since first subject enrolled]

  CBR is the percentage of participants whose best overall response is either CR, PR, or stable disease (SD) per CRAC according to RECIST version 1.1 from the date of randomization until disease progression or death, whichever occurs first.

- CBR per the investigator assessment based on RECIST v1.1 [Time Frame: Approximately 31 months since first subject enrolled]

  CBR is the percentage of participants whose best overall response is either CR, PR, or stable disease (SD) per investigator from the date of randomization until disease progression or death, whichever occurs first.

- Duration of response (DOR) per the CRAC assessment [Time Frame: Approximately 31 months since first subject enrolled]

  DOR is the time from the initial objective response (CR/PR) by CRAC to disease progression or death, whichever occurs first.

- DOR per the investigator assessment [Time Frame: Approximately 31 months since first subject enrolled]

  DOR is the time from the initial objective response (CR/PR) by investigator to disease progression by investigator or death, whichever occurs first.

Estimated Enrollment:	740
Actual Study Start Date:	February 7, 2017
Estimated Study Completion Date:	April 1, 2020
Estimated Primary Completion Date:	November 14, 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Rovalpituzumab tesirine/dexamthasone Rovalpituzumab tesirine/dexamethasone every 6 weeks (q6 wk); omitting every third cycle	Drug: Rovalpituzumab tesirine Rovalpituzumab tesirine 0.3 mg/kg administered intravenously Day 1 of each 6-week cycle, omitting every third cycle Drug: Dexamethasone Dexamethasone 8 mg administered orally (PO) twice daily on Day -1, Day 1 (the day of dosing), and Day 2 of each 6 week cycle, omitting every third cycle.
Experimental: Placebo Placebo q6 wk; omitting every third cycle	Drug: Placebo for rovalpituzumab tesirine Placebo for rovalpituzumab tesirine administered intravenously Day 1 of each 6-week cycle, omitting every third cycle Drug: Placebo for dexamethasone Placebo for administered orally (PO) twice daily on Day -1, Day 1 (the day of dosing), and Day 2 of each 6 week cycle, omitting every third cycle.

Eligibility

Ages Eligible for Study:	18 Years to 99 Years (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histologically or cytologically confirmed extensive-stage disease small cell lung cancer (ED SCLC) with ongoing clinical benefit (stable disease [SD], partial response [PR], or complete response [CR]) following completion of 4 cycles of first-line platinum-based therapy
- At least 3 but no more than 9 weeks between the administration of the last cycle of platinum-based chemotherapy and randomization.
- Participants with a history of central nervous system (CNS) metastases prior to the initiation of first-line platinum-based chemotherapy must have received definitive local treatment and have documentation of stable or improved CNS disease status
- Eastern Cooperative Oncology Group (ECOG) performance score of 0 or 1
- Participants must have adequate bone marrow, renal and hepatic function
- Availability of archived or representative tumor material for assessment of DLL3 expression

Exclusion Criteria:

- Any prior systemic chemotherapy, small molecule inhibitors, immune checkpoint inhibitors, other monoclonal antibodies, antibody-drug conjugates, radioimmunoconjugates, T-cell or other cell-based or biologic therapies, or any other anti-cancer therapy than that described in inclusion criteria
- Any disease-directed radiotherapy (except prophylactic cranial irradiation or pre-planned radiotherapy for CNS metastases present prior to start of first-line therapy and non-progressing) after last dose of first-line chemotherapy.
- Prior exposure to a pyrrolobenzodiazepine (PBD)- or indolinobenzodiazepine-based drug, prior participation in a rovalpituzumab tesirine clinical trial, or known hypersensitivity or other contraindications to rovalpituzumab tesirine or excipient contained in the drug formulation.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT03033511

Contacts

Contact: AbbVie_Call Center 847.283.8955 abbvieclinicaltrials@abbvie.com

Show 48 Study Locations

Sponsors and Collaborators

AbbVie

Investigators

Study Director: AbbVie Inc AbbVie

More Information

Responsible Party:	AbbVie
ClinicalTrials.gov Identifier:	NCT03033511 History of Changes
Other Study ID Numbers:	**M16-298** 2016-003503-64 (EudraCT Number)
Study First Received:	January 25, 2017
Last Updated:	May 31, 2017

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

Keywords provided by AbbVie:
Rovalpituzumab tesirine
Cancer
Platinum-Based Chemotherapy
Extensive-Stage Small Cell Lung Cancer (ED SCLC)
first-line chemotherapy

Additional relevant MeSH terms:

Lung Neoplasms	Anti-Inflammatory Agents
Small Cell Lung Carcinoma	Antiemetics
Respiratory Tract Neoplasms	Autonomic Agents
Thoracic Neoplasms	Peripheral Nervous System Agents

Neoplasms by Site
Neoplasms
Lung Diseases
Respiratory Tract Diseases
Carcinoma, Bronchogenic
Bronchial Neoplasms
Dexamethasone acetate
Dexamethasone
Dexamethasone 21-phosphate
BB 1101

Physiological Effects of Drugs
Gastrointestinal Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Antineoplastic Agents, Hormonal
Antineoplastic Agents
Protease Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action

ClinicalTrials.gov processed this record on June 12, 2017