A Study of [177Lu]Lu-DOTA-TATE in Newly Diagnosed ES-SCLC Patients in Combination With Carboplatin, Etoposide and Atezolizumab

Last Update: Jul 22, 2025
A Phase Ib/II Dose Finding Study Assessing Safety and Efficacy of [177Lu]Lu-DOTA-TATE in Newly Diagnosed Extensive Stage Small Cell Lung Cancer (ES-SCLC) in Combination With Carboplatin, Etoposide, and Atezolizumab in Induction and With Atezolizumab in Maintenance Phase
ClinicalTrials.gov Identifier:
NCT05142696
Novartis Reference Number:CAAA601A42101
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This study aims to establish a safe and well tolerated dose of \[177Lu\]Lu-DOTA-TATE in combination with carboplatin, etoposide and atezolizumab in this setting and to assess preliminary efficacy of this combination treatment versus the combination of carboplatin, etoposide, and atezolizumab.The study will be essential to assess a new potential therapeutic option in participants with this aggressive cancer type. The study for each participant consists of a Screening period, a Treatment period that includes an Induction treatment period and a Maintenance treatment period, and a Follow-up period.

The study will consist of a Phase Ib dose escalation with concurrent backfill part and a randomised controlled Phase II part.

During the screening period of up to 28 days before starting SCLC treatment, each participant will be assessed for somatostatin receptor (SSTR) expression by \[68Ga\]Ga-DOTA-TATE imaging PET/scan.

The dose escalation part in this study will be guided by the dose limiting toxicity (DLT) rate observed during the DLT period. To achieve a more robust dataset and to aid dose decisions, additional participants may be backfilled in each dose level.

Upon declaring RD, a 1:1 randomised Phase II with approximately 140 participants with newly diagnosed ES-SCLC will be enrolled and receive either \[177Lu\]Lu-DOTA-TATE at the RD in combination with carboplatin, etoposide and atezolizumab (experimental arm) or carboplatin, etoposide and atezolizumab alone (control arm).

Condition
Extensive Stage Small Cell Lung Cancer
Phase
Phase1, Phase2
Overall Status

Recruiting
Number of Participants
200
Start Date
Jul 13, 2022
Completion Date
Mar 23, 2029
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Atezolizumab

Atezolizumab 1200 mg on Day 1 from Cycle 2 every 3 weeks in induction and maintenance period
Other

Carboplatin

Four cycles of carboplatin AUC 5 on Day 1 every 3 weeks (Weeks 1, 4, 7 and 10) in induction period
Other

Etoposide

Four cycles of etoposide 100 mg/m2 on Day 1-3, every 3 weeks (Weeks 1, 4, 7 and 10) in induction period
Drug

[177Lu]Lu-DOTA-TATE

Solution for infusion of \[177Lu\]Lu-DOTA-TATE will be administered as follows: * 2 administrations during the induction period on either Day 3, 4 or 5 of Week 1 and on Week 7 Day 3 * 1 to 4 administrations during the maintenance period on Week 13 Day 1, Week 16 Day 1, Week 19 Day 1 and Week 22 Day 1, depending on the dose assessed
Drug

[68Ga]Ga-DOTA-TATE

2 MBq/kg of body weight (0.054 mCi/kg), with a minimum dose of 100 MBq (2.7 mCi) and maximum dose of 200 MBq (5.4 mCi)

Eligibility Criteria

Key Inclusion Criteria:

* Participant is \>= 18 years on the day of signing informed consent form
* Histologically or cytologically confirmed ES-SCLC

* Presence of measurable disease (at least one target lesion) according to RECIST v1.1 demonstrating moderate or higher uptake of \[68Ga\]Ga-DOTA-TATE on PET imaging; in case of liver involvement, at least one liver lesion \> = 1 cm
* No prior systemic treatment for ES-SCLC (except the first cycle of chemotherapy with or without atezolizumab of the induction period
* ECOG status =\< 1
* Provision of tumor tissue to support exploratory biomarker analysis
* Life expectancy of \>= 6 months

Key Exclusion Criteria:

* Participant has received prior therapy with an antibody or drug against immune checkpoint pathways
* Active autoimmune diseases or history of autoimmune diseases that may relapse
* Severe chronic or active infections (including active tuberculosis, HBV, or HCV infection) requiring systemic antibacterial, antifungal or antiviral therapy within 2 weeks before Cycle 1 Day 1
* Any major surgical procedure requiring general anesthesia =\< 28 days before Cycle 1 Day 1
* History or current diagnosis of electrocardiogram (ECG) abnormalities indicating significant risk of safety for participants participating in the study
* Known hypersensitivity to the active substances or any of the excipients of the study drugs
* Concurrent participation in another therapeutic clinical study
* Prior administration of therapeutic radiopharmaceuticals

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Novartis Investigative Site

Recruiting

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Recruiting

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