Protocol IMFORTE (ROCHE)

A Phase III, Open-Label Study of Maintenance Lurbinectedin in Combination With Atezolizumab Compared With Atezolizumab in Participants With Extensive-Stage Small-Cell Lung Cancer (IMforte).

This is the trial summary as assessed on clinicaltrials.gov on 08/09/2022.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/show/NCT05091567

Study design

Arm	Behandeling
Experimental: Atezo + Lurbinectidin Induction phase: participants will receive standard of care atezolizumab on Day 1 of each 21-day cycle in combination with carboplatin on Day 1 and etoposide on Days 1, 2, and 3 of each 21-day cycle for 4 cycles. Maintenance phase: participants will receive atezolizumab on Day 1 of each 21-day cycle in combination with lurbinectedin on Day 1 of each 21-day cycle.	Drug: Atezolizumab Atezolizumab will be administered intravenously at a fixed dose of 1200 mg on Day 1 of each 21-day cycle for 4 cycles in the induction phase. Atezolizumab will be administered intravenously at a fixed dose of 1200 mg on Day 1 of each 21-day cycle in the maintenance phase. Drug: Lurbinectedin Lurbinectedin 3.2 mg/m² will be administered intravenously on Day 1 of each 21-day cycle in the maintenance phase. Drug: Carboplatin SOC – induction phase Drug: Etoposide SOC – induction phase
Comparator: Atezolizumab Induction phase: participants will receive standard of care atezolizumab on Day 1 of each 21-day cycle in combination with carboplatin on Day 1 and etoposide on Days 1, 2, and 3 of each 21-day cycle for 4 cycles. Maintenance phase: participants will receive atezolizumab on Day 1 of each 21-day cycle.	Drug: Atezolizumab Atezolizumab will be administered intravenously at a fixed dose of 1200 mg on Day 1 of each 21-day cycle for 4 cycles in the induction phase. Atezolizumab will be administered intravenously at a fixed dose of 1200 mg on Day 1 of each 21-day cycle in the maintenance phase. Drug: Carboplatin SOC – induction phase Drug: Etoposide SOC – induction phase

Inclusion Criteria:

Induction Phase

- ECOG PS of 0 or 1
- No prior systemic therapy for ES-SCLC
- Treatment-free for at least 6 months since last chemo/radiotherapy, among those treated (with curative intent) with prior chemo/radiotherapy for limited-stage SCLC
- Histologically or cytologically confirmed ES-SCLC
- Adequate hematologic and end-organ function to receive 4 cycles of induction treatment with carboplatin, etoposide and atezolizumab
- Measurable disease, as defined by RECIST v1.1
- Negative HIV test and no evidence of active Hepatitis B or Hepatitis C at screening

Maintenance Phase

- ECOG PS of 0 or 1
- Ongoing response or stable disease per RECIST 1.1 after 4 cycles of induction therapy
- Toxicities attributed to prior induction anti-cancer therapy or PCI resolved to Grade <=1
- Adequate hematologic and end-organ function

Exclusion Criteria:

Induction Phase

- CNS metastases
- Active or history of autoimmune disease or deficiency
- History of malignancies other than SCLC within 5 years prior to enrollment
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies, or lurbinectedin or trabectedin
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Treatment with investigational therapy within 28 days prior to enrollment

Maintenance Phase

- CNS metastases
- Receiving consolidative chest radiation
- Severe infection within 2 weeks prior to randomization into the maintenance
- Treatment with therapeutic oral or IV antibiotics at the time of randomization