Durvalumab plus platinum–etoposide in first-line treatment of extensive-stage small-cell lung cancer (CANTABRICO): a Spanish phase IIIb single arm, real world study. NCT04712903

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BACKGROUND

- Small-cell lung cancer (SCLC) represents approximately 13% of all newly diagnosed lung cancers.
- Most patients have extensive-stage (ES) disease at diagnosis, and prognosis remains poor, with a 5-year survival less than 2% despite receiving the standard of care.
- Four to six cycles of etoposide (ET) in combination with either cisplatin (CPT) or carboplatin (CP) (platinum (PT) –etoposide) is the standard of care.
- CASPIAN trial showed that durvalumab (D) in combination with PT-ET in treatment-naive patients with ES-SCLC improved overall survival (*Paz-Ares, Lancet 2019*).
- There is limited information in patients with ECOG PS 2, specific comorbidities, controlled autoimmune diseases, or in patients where the investigator can expect benefit from a prophylactic cranial irradiation.
- Therefore, there remains an unmet need for additional data in the use of D plus PT-ET as first-line treatment for unselected patients in real clinical practice.

Objectives

This study will assess safety and effectiveness of D plus PT-ET in a real world ES-SCLC population in spain.

Primary objective

- Safety profile of D plus PT-ET as first-line treatment

Secondary objectives

- Effectiveness of D plus PT-ET as first-line treatment
- Impact of D plus PT-ET as first-line treatment.
- Health care resources use related to management of ES-SCLC patients treated D plus PT-ET
- To describe the impact of D plus PT-ET as first-line treatment for patients with ES-SCLC on patients' disease-related symptoms and Health Related Quality of Life (HRQoL) and (PROs).
- Immune & biological characteristics of populations, basal, at the beginning of maintenance and at progression

Study design

Phase IIIb open-label, single-arm, multi-center Clinical Trial of Durvalumab + platinum-etoposide as first-line treatment of patients with ES-SCLC.

- Treatment naive ES-SCLC, including progressive disease after at least 6 months without treatment for LS-SCLC
- WHO PS 0-2*
- Eligible to receive platinum-based 1L therapy
- Patients with either asymptomatic or treated and stable brain metastases are permitted
- Adequate hematologic and organ function
- Life expectancy >12 weeks
- Body weight >30 kg

1 → **Durvalumab + PT-ET, 4-6 cycles q3w** → 2 → **Durvalumab q4w until PD** → 3 → **Overall Survival Follow up**

Blood Sample: 1, 2 & 3

Tumor Sample: 1 & 3

*PS2 limited to ≤30% ITT

- Durvalumab (1500 mg) d1 q3w during 4-6 cycles; then q4w until PD
- Cisplatin (75-80 mg/m^2) or Carboplatin (AUC5) d1 q3w for 4-6 cycles
- Etoposide (80-100 mg/m^2) d1-3 q3w for 4-6 cycles

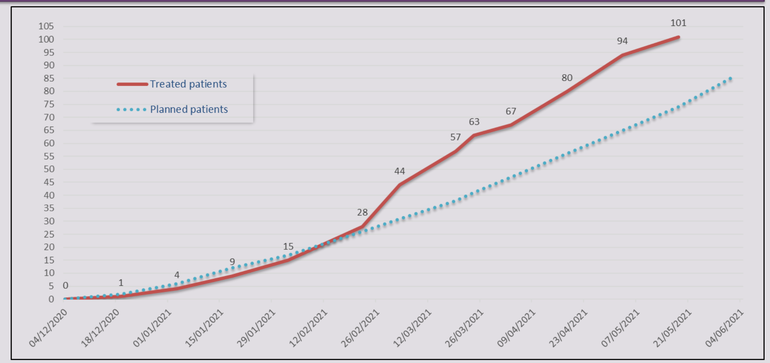
Primary endpoint:
Safety (incidence of Grade ≥3 AE, imAE)

Secondary endpoints:
PFS, OS, ORR, DOR, 6/12m PFS, 6/12/18m OS, 12m DOR, TTD, safety and tolerability, PRO & health care resources use.

Study progress

❖A sample size of **85** patients has been estimated to be recruited during **6 months** in the Medical Oncology Departments of 30 sites in Spain. However, recruitment has been more successful that expected, getting a sample size of **101 patients** in **31** of the 35 sites that finally participated.

❖The study began to recruit patients in December 2020, and recruitment was completed in April 2021.



Disclosures

Luis Paz-Ares, Principal investigator of this study, reports receiving honoraria for scientific advice or as a speaker for Amgen, AstraZeneca, Bayer, Blueprint Medicines, Bristol-Myers Squibb, GSK, Ipsen, Janssen, Eli Lilly, Merck Serono, Merck Sharp & Dohme, Miriati, Novartis, PharmaMar, Pfizer, Roche, Sanofi, Takeda, Tesaro; is a board member for Altum Sequencing; and has received grants for the institution from Alkermes, Amgen, AstraZeneca, Bristol-Myers Squibb, Daiichi Sankyo, IO Biotech, Janssen-Cilag international NV, Eli Lilly, Merck Sharp & Dohme corp, Novartis, Pfizer, Pharmamar, Roche, Sanofi, Takeda and Tesaro.

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