Phase IIIb study of durvalumab plus platinum–etoposide in first-line treatment of extensive-stage small-cell lung cancer (CANTABRICO): treatment patterns and chemotherapy improvement

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 the remaining use of standard care chemotherapy [four to six cycles of etoposide (ET) in combination with cisplatin or carboplatin (PT–ET)].

CANTABRICO trial showed that durvalumab (D) in combination with platinum-etoposide in treatment-naive patients with ES-SCLC improved overall survival (Par- Ares, Lancet 2019).

There is limited information in patients with EGFR P.5, specific comorbidities, controlled autoimmune diseases, or in patients where the investigator can expect to disrupt current from a prophylactic corticosteroid use.

Therefore, there remains an unmet need for additional data in the use of D plus PT–ET for first-treatment for unselected patients in real clinical practice.

This study will assess safety and effectiveness of durvalumab plus platinum–etoposide as first-line treatment.

Secondary objectives

Effectiveness of durvalumab plus platinum-etoposide as first-line treatment.

Impact of durvalumab plus platinum-etoposide as first-line treatment.

Health care resource use related to management of extensive-stage small-cell lung cancer patients treated durvalumab plus platinum-etoposide.

To describe the impact of durvalumab plus platinum-etoposide as first-line treatment for patients with extensive-stage small-cell lung cancer on patients’ disease-related symptoms and Health Related Quality of Life (HRQoLs) and (HRQoL).

Immune & biological characteristics of populations, at baseline, during maintenance and at progression.

STUDY DESIGN

Phase IIIb, single-arm, multi-center Clinical Trial (NCT04712903) of durvalumab + platinum-etoposide as first-line treatment of patients with extensive-stage small-cell lung cancer.

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

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TREATMENT EXPOSURE

<table>
<thead>
<tr>
<th>CASPIAN (N, %)</th>
<th>CANTABRICO (N, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with platinum dose</td>
<td>85 (84)</td>
</tr>
<tr>
<td>Cycles</td>
<td>10 (10)</td>
</tr>
<tr>
<td>Patients receiving ≥4 cycles</td>
<td>10 (10)</td>
</tr>
<tr>
<td>Durvalumab doses, median (IQR)</td>
<td>6 (5-11)</td>
</tr>
</tbody>
</table>

DISCLOSURES

1. Patients with prior diagnosis of brain metastases were eligible.

2. Patients with prior neurologic symptoms or brain metastases were eligible.

3. Patients with unconfirmed PR for CANTABRICO only; all CASPIAN responses shown were confirmed.

4. Four patients died, but did not have all admissions evaluated and 1 discontinued due to AD.

5. A phase 3 trial assessing safety and effectiveness of durvalumab plus platinum–etoposide as first-line treatment of patients with extensive stage small-cell lung cancer on patients’ disease-related symptoms and Health Related Quality of Life (HRQoLs) and (HRQoL).

6. Immune & biological characteristics of populations, at baseline, during maintenance and at progression.

CONCLUSIONS

CANTABRICO study showed that increasing numbers of cycles of PT–ET didn’t have a detrimental effect in safety.

40% of patients received 5 or more cycles of PT–ET (33 cycles), and none of them discontinued due to toxicity.

Most common AE’s leading to treatment modification were hematologic, as expected for PT–ET.

The clinical benefit rate was similar to that obtained in the CASPIAN study.

In this study reflecting a broader patient population and treatment practices in Spain, the safety profile and clinical benefit of durvalumab was consistent with CASPIAN.