Atezolizumab (ATZ) plus Carboplatin (Cb) and Etoposide (Eto) in patients with untreated extensive-stage small-cell lung cancer (ES-SCLC): results from the intermediate analysis of MAIRIS trial

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INTRODUCTION

Small cell lung cancer (SCLC) accounts for approximately 15% of all lung cancers and is characterized by early development of metastatic disease and hence poor prognosis. Atezolizumab (ATZ) is a humanized monoclonal anti–programmed death ligand 1 (PD-L1) antibody that results in PD-L1–programmed cell death (PD-1/PD-L1) signaling blockade.

The results of the Maestro133 Phase II study showed that the addition of ATZ to 4 cycles of carboplatin (Cb) and etoposide (Eto) in extended stage (ES) SCLC was associated with significantly longer overall survival (OS) and progression-free survival (PFS) compared to chemotherapy alone, with a safety profile consistent with the defined toxic effects of the individual agents.

OBJECTIVES

The purpose of the present Phase III trial (MAIRIS) was to evaluate the safety and efficacy of ATZ in combination with Cb plus Eto in patients with newly diagnosed ES-SCLC, including those not previously evaluated in the pivotal trial.

METHODS

MAIRIS (NCT019-061147) is a multicenter, open-label, single-arm, phase IIIb trial conducted in 23 sites, aimed at evaluating the safety and efficacy of ATZ + Cb-Eto in patients with newly diagnosed ES-SCLC, including those not previously evaluated in the pivotal trial.

PATIENTS AND METHODS

Main inclusion criteria
- Histologically or cytologically confirmed ES SCLC, with measurable disease
- ≥ 18 years old
- ECOG Performance Status 0-2
- Life expectancy > 12 weeks
- No previous systemic treatment for ES-SCLC
- Adequate hematologic and end-organ function
- Smoking status: current, former or never smoker
- Signed informed consent

Main exclusion criteria
- Untreated brain metastases at baseline
- Prior thoracic irradiation during the study
- Any serious uncontrolled disease or concomitant condition that, in the Investigator’s discretion, could impair the safety and efficacy evaluation
- Women of childbearing potential
- Chemotherapy within 2 weeks of study entry

RESULTS

Overall response rate (ORR)
In the overall ITT population, 111 patients (71.7%, 95% CI, 64.1% to 78.1%) had response and 44 (28.4%, 95% CI, 20.5% to 36.0%) did not respond to treatment. The proportion of responders was higher in those who performed 5-6 cycles (75 patients, 94.3%) than in those who performed 3 cycles (36 patients, 27%).

Progression-free survival (PFS)
The median PFS in the overall ITT population was 5.5 months (95% CI, 5.3 to 5.8 months). Figure 1 shows the results of PFS by subgroup: Kaplan-Meier estimate (ITT set) for patients treated for 3, 4, and 5-6 cycles. The results of efficacy observed up to the cut-off date (median follow-up 10.5 months) were consistent with the overall results of the MAIRIS study in terms of ORR and PFS. The OS results are presented in Figure 2, which shows the results of OS by subgroup: Kaplan-Meier estimate (ITT set) for patients treated for 3, 4, and 5-6 cycles.

CONCLUSIONS

The results of safety in the induction phase of the MAIRIS study are in line with the known safety profile of ATZ, Cb and Eto. More than half of the patients continued the induction up to 5-6 cycles, according to the investigator’s choice based on safety and efficacy evaluation. The longer benefit for patients receiving 5-6 cycles of chemotherapy in comparison with those 3/4 cycles observed in the MAIRIS study, might be due to the inclusion of patients with a worse prognosis. Instead mPFS and ORR were comparable. The final analysis of the MAIRIS study will provide more data on the safety and efficacy of ATZ in combination with Cb plus Eto for the treatment of ES-SCLC patients managed in real-world conditions.

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