

RATIONALE-312

1L ES-SCLC



RATIONALE-312 Trial Design



Phase 3

Study Identifier:
BGB-A317-312, NCT04005716

Primary Endpoint: OS in ITT

Key Secondary Endpoints: INV-assessed PFS, ORR, DoR, DCR, and HRQoL

Key eligibility criteria

- Histologically or cytologically confirmed ES-SCLC
- No prior systemic treatment for ES-SCLC
- ECOG PS 0 or 1

Stratification factors

- ECOG PS (0 vs 1)
- Choice of platinum (carboplatin vs cisplatin)
- Brain metastasis (yes vs no)

Treatment

Induction phase (Up to 4 cycles)

**Tislelizumab 200 mg IV
Q3W + carboplatin or
cisplatin + etoposide
(n=227)**

**Placebo
+ carboplatin or cisplatin
+ etoposide
(n=230)**

R 1:1

Maintenance phase^a

**Tislelizumab
200 mg IV
Q3W**

Placebo

Treatment until unacceptable toxicity, disease progression, or loss of clinical benefit

Follow-up

Safety and survival

^aPatients may continue tislelizumab monotherapy if investigator considers it beneficial beyond PD; crossover not permitted.

IL=1st line, DCR=disease control rate, DoR=duration of response, ECOG PS=Eastern Cooperative Oncology Group performance status, ES-SCLC=extensive-stage small cell lung cancer, HRQoL=health-related quality of life, INV=investigator, ITT=intent-to-treat, IV=intravenous, ORR=objective response rate, OS=overall survival, PD=progressive disease, PFS=progression-free survival, R=randomized, Q3W=every 3 weeks.

1. Cheng Y et al. J Thorac Oncol. 2024;19:1073-1085. T1P; 2. ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT04005716>. Jul 23, 2024.