

A Randomized, Open-Label, Phase 3 Study of ZL-1310, a DLL3 Antibody-Drug Conjugate (ADC), Compared to Investigator's Choice Therapy in Participants with Relapsed Small Cell Lung Cancer

Protocol v.3.0
14 Nov 2025

RECRUITMENT TIPS:

This study allows 1L maintenance lurbi and prior tarlatamab treatment.

MOA:

ZL-1310 is an ADC that targets DLL3 and contains a topoisomerase I inhibitor payload.



Eligible Patients

- ES-SCLC
- Must have progressed following the platinum-based regimen
- Received only 1 line of prior systemic therapy, or 1 line of chemotherapy followed by tarlatamab
- At least one measurable lesion
- ECOG 0-1

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Zocilurtatug pelitecan (ZL-1310)
1.6 mg/kg Q3W

Investigator's choice of therapy

Stratification factors

- Brain mets: Yes vs No
- Prior systemic treatment*: 1L CTFI ≥90 days vs. 1L with CTFI <90 days vs. 2L
- Previously treated with tarlatamab: Yes or No

Primary endpoints: BICR-ORR, OS
Secondary endpoints: PFS, DoR, safety, PROs



SAFETY

- ILD/pneumonitis
- Anemia
- Neutropenia
- Febrile Neutropenia
- Thrombocytopenia



KEY ELIGIBILITY

- Confirmed diagnosis of SCLC
- Archival tumor tissue or fresh tumor tissue must be submitted at screening. DLL3 expression will be assessed retrospectively.
- Must have received only 1L plt-based chemo and had documented disease progression during/after most recent systemic tx
 - Prior 1L systemic tx should be plt-base chemo with an anti-PD(L)1 agent
 - Maintenance tx with anti-PD-(L1)/lurbinectedin/tarlatamab does not count as a separate line of tx
 - Plt-base chemo for limited-stage SCLC is considered one line of tx
 - 2L systemic tx is **not allowed**, except for tarlatamab
- Measurable disease according to RECIST v1.1
- Prior tx with ADC containing any topoisomerase I inhibitor payload **are excluded**
- Treated and stable CNS metastases are eligible (parenchymal).
 - Metastasis to leptomeninges **are excluded**
- Untreated and asymptomatic CNS metastases are eligible but must not require steroids and/or anti-convulsants, nor local tx