A Randomized, Multicenter, Open-Label, Phase 3 Study of Lurbinectedin Single-Agent or Lurbinectedin in Combination With Irinotecan Versus Investigator's Choice (Topotecan or Irinotecan) in Relapsed Small Cell Lung Cancer Patients (LAGOON Trial) – (NCT05153239)

Study Overview

Purpose	To evaluate and compare the activity and safety of either lurbinectedin monotherapy or the combination of lurbinectedin and irinotecan versus investigator's choice of control therapy in patients with SCLC who failed one prior line of treatment with platinum-containing chemotherapy
Condition(s)	Relapsed SCLC
Drug(s)	• Lurbinectedin monotherapy • Lurbinectedin + irinotecan • Topotecan or irinotecan
Study Phase	Phase 3
Participating Countries	Global

Selected Outcome Measures

Primary Outcome Measure:

- OS

Secondary Outcome Measures:

- PFS by IRC
- PFS by IA
- ORR by IRC
- ORR by IA
- OS rate at 12 months
- OS rate at 24 months
- PFS rate at 6 months by IRC
- PFS rate at 6 months by IA
- PFS rate at 12 months by IRC
- PFS rate at 12 months by IA
- DOR by IRC
- DOR by IA
- Patient-reported outcomes

Abbreviations: DOR, duration of response; IA, investigator assessment; IRC, independent review committee; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; SCLC, small cell lung cancer.

Contact Information:

https://www.clinicaltrials.gov (Identifier: NCT05153239)

Key Eligibility Criteria

Key Inclusion Criteria:

- Patients must be ≥18 years of age
- Patients must have histologically or cytologically confirmed diagnosis of SCLC
- Patients must have received 1 prior line of platinum-containing chemotherapy with/without anti–PD-1 or anti–PD-L1
- Patients must have a chemotherapy-free interval of ≥30 days
- Patients with a history of central nervous system metastases can participate provided they are pretreated, asymptomatic, and radiologically stable for ≥4 weeks, as indicated by repeat imaging, and do not require steroid treatment for ≥7 days before the first dose of study treatment
- Patients must have an Eastern Cooperative Oncology Group performance status of ≤2
- Patients must have adequate hematologic, renal, metabolic, and hepatic function

Key Exclusion Criteria:

- Patient is platinum-naïve or has been pretreated with >1 prior chemotherapy regimen
- Patient has received prior treatment with lurbinectedin, trabectedin, PM14, or topoisomerase I inhibitors
- Patient has active or untreated central nervous system metastases and/or carcinomatous meningitis
- Patient has received prior radiotherapy in >35% of the bone marrow or has an impending need for radiotherapy
- Patient has received a prior allogeneic bone marrow or stem cell transplant
- Patient has received a live or live-attenuated vaccine within 30 days of the first study dose
- Patient has an active infection or concomitant condition that could substantially increase the risk associated with the patient's participation in the study

Treatment Regimen

- Experimental monotherapy arm: Lurbinectedin 3.2 mg/m^2 administered by IV infusion every 3 weeks
- Experimental combination arm: Lurbinectedin 2.0 mg/m^2 IV every 3 weeks + irinotecan 75 mg/m^2 IV on Days 1 and 8 every 3 weeks
- Control arm: Investigator's choice of
  - Irinotecan 350 mg/m^2 IV every 3 weeks
  - Topotecan 2.3 mg/m^2 orally or 1.5 mg/m^2 IV on Days 1 to 5 every 3 weeks

Abbreviations: IV, intravenous; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; PM14, ecubectedin; SCLC, small cell lung cancer.