Real-World Observational Study in Patients With Extensive-Stage SCLC Receiving Lurbinectedin (Jazz EMERGE 402) – (NCT04894591)

Study Overview

Purpose	To assess the effectiveness and safety of lurbinectedin in adult patients with extensive-stage SCLC in real-world clinical practice
Condition(s)	Extensive-stage SCLC
Drug(s)	Lurbinectedin
Study Phase	Phase 4
Participating Countries	US and Canada

Selected Outcome Measures

Primary Outcome Measure:

- Overall response rate

Secondary Outcome Measures:

- OS
- PFS
- DOR
- DCR
- Time to response to lurbinectedin
- Distribution of treatment patterns
- Safety and tolerability including SAEs and AESIs
- Health-related quality of life using patient-reported outcome questionnaires
- Effectiveness (OS, PFS, DOR, and DCR) in other subgroups of interest
- Safety and tolerability (including SAEs and AESIs) in other subgroups of interest

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http://www.clinicaltrials.gov
(Identifier: NCT04894591)

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Key Eligibility Criteria

Key Inclusion Criteria:

- Patients must be ⩾18 years of age
- Patients must have initiated or plan to receive lurbinectedin treatment in line with local lurbinectedin prescribing information
- The decision to initiate treatment with lurbinectedin must have been made per the investigator's routine treatment practice, prior to enrollment in the study
- Patients initiating lurbinectedin for second-line treatment
- Patients sensitive to platinum-based chemotherapy with CTFI ⩾180 days
- ECOG performance status ⩽1

Key Exclusion Criteria:

- Patient has discontinued a prior lurbinectedin treatment due to adverse events
- Patient has received >2 cycles of lurbinectedin treatment in their current treatment schedule
- Patient has received treatment with any investigational agent within 30 days prior to the first lurbinectedin infusion or plans to use another investigational agent while receiving lurbinectedin
- Known CNS involvement prior to lurbinectedin treatment
- Patients treated with lurbinectedin in later lines rather than second-line treatment

Treatment Regimen

- Lurbinectedin will be administered by intravenous infusion over 60 minutes every 21 days
- Characteristics of lurbinectedin administration will be collected at each cycle: date of each lurbinectedin infusion and total dose prescribed and received

AESI, adverse event of special interest; CNS, central nervous system; CTFI, chemotherapy-free interval; DCR, disease control rate; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; OS, overall survival; PFS, progression-free survival; SAE, serious adverse event; SCLC, small cell lung cancer.

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