ZEPZELCA®
(lurbinectedin) for injection 4 mg

For adult patients with metastatic small cell lung cancer (mSCLC) with disease progression on or after platinum-based chemotherapy

Could ZEPZELCA be an appropriate choice for your patient?

Actor portrayals.

INDICATION

ZEPZELCA® (lurbinectedin) is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Myelosuppression

ZEPZELCA can cause myelosuppression. In clinical studies of 554 patients with advanced solid tumors receiving ZEPZELCA, Grade 3 or 4 neutropenia occurred in 41% of patients, with a median time to onset of 15 days and a median duration of 7 days. Febrile neutropenia occurred in 7% of patients.

Sepsis occurred in 2% of patients and was fatal in 1% (all cases occurred in patients with solid tumors other than SCLC). Grade 3 or 4 thrombocytopenia occurred in 10%, with a median time to onset of 10 days and a median duration of 7 days. Grade 3 or 4 anemia occurred in 17% of patients.

Please see Important Safety Information throughout and full Prescribing Information.

ZEPZELCA® (lurbinectedin) was evaluated in

A phase 2, open-label, multicenter, single-arm study[1,2]

PATIENTS

Adult patients with small cell lung cancer with disease progression who had received at least 1 prior line of platinum-based chemotherapy

- **ECOG PS ≤2**
- **n=105**

TREATMENT

ZEPZELCA 3.2 mg/m² administered

- As a **60-minute** infusion every **21 days**
- Treatment continued until disease progression or unacceptable toxicity

ENDPOINTS

PRIMARY:

- Overall response rate as assessed by study investigators[2]

SECONDARY:

- Duration of response[2]
- Progression-free survival[2]
- Overall survival[2]

EXPLORATORY:

- Proportion of patients with disease control (complete response + partial response + stable disease)[2,3]

Primary endpoint and secondary endpoints, except overall survival, were analyzed by an independent review committee to confirm investigator assessments.[2]

SAFETY The safety profile of ZEPZELCA was based on[1]:

- A pool of **554 patients** with advanced solid tumors
  - Includes the 105 patients with metastatic small cell lung cancer in the phase 2 study
- Exposure to ZEPZELCA as a single agent at a dose of **3.2 mg/m²** given intravenously every 21 days

Please see Important Safety Information throughout and full Prescribing Information.

Baseline Characteristics[1]	
	N=105
Median age (years)	60
Age range (years)	40–83
≥65 years	35%
Male	60%
White	75%[a]
ECOG PS 0–1	92%
Former/current smokers	92%

[a]1% were Asian, 1% were Black, and 23% were not reported.

Patient Population According to Chemotherapy-Free Interval (CTFI)[1–3]

OVERALL POPULATION N=105

Platinum resistant (n=45)[2,3]		Platinum sensitive (n=60)[2,3]	
Platinum resistant: Recurrence or progression **<90 days** after the last dose of platinum-containing chemotherapy (CTFI <90 days)[1]		**Platinum sensitive:** Recurrence or progression **≥90 days** after the last dose of platinum-containing chemotherapy (CTFI ≥90 days)[1]	
<30 days n=21	**30 to <90 days n=24**	**90 to <180 days n=40**	**≥180 days n=20**

ECOG PS=Eastern Cooperative Oncology Group Performance Status.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Myelosuppression *(continued)*

Administer ZEPZELCA only to patients with baseline neutrophil count of at least 1,500 cells/mm³ and platelet count of at least 100,000/mm³.

Monitor blood counts including neutrophil count and platelet count prior to each administration. For neutrophil count less than 500 cells/mm³ or any value less than lower limit of normal, the use of G-CSF is recommended. Withhold, reduce the dose, or permanently discontinue ZEPZELCA based on severity.

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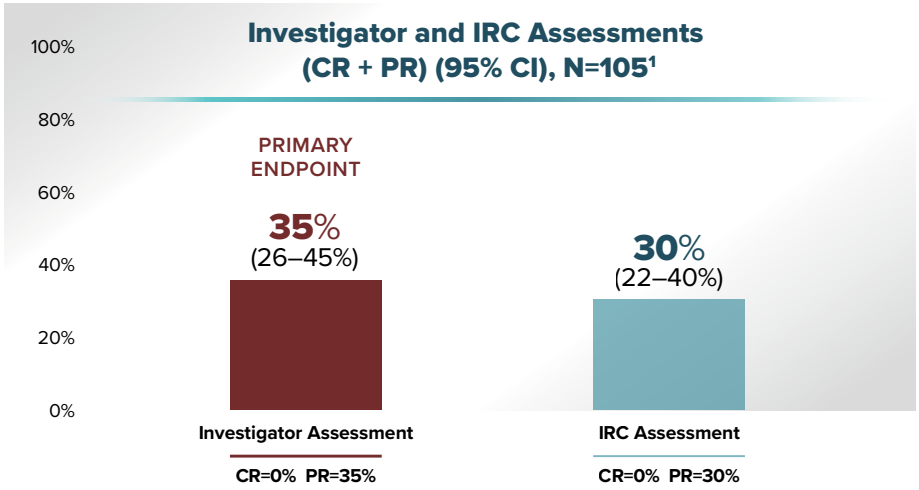
Overall response rate was evaluated in both platinum-resistant and platinum-sensitive groups



In the overall population,
>1 IN 3 PATIENTS ACHIEVED AN OVERALL RESPONSE
with ZEPZELCA by the investigator assessment[1]

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

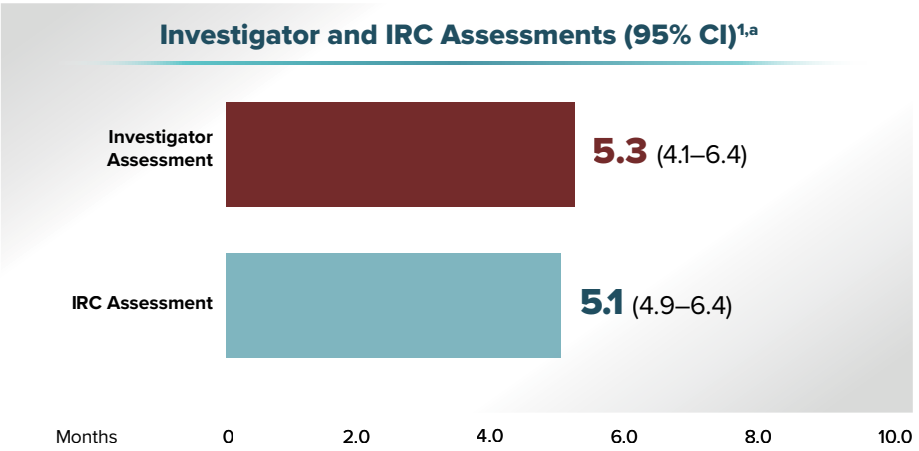
Hepatotoxicity

ZEPZELCA can cause hepatotoxicity. In clinical studies of 554 patients with advanced solid tumors receiving ZEPZELCA, Grade 3 elevations of ALT and AST were observed in 6% and 3% of patients, respectively, and Grade 4 elevations of ALT and AST were observed in 0.4% and 0.5% of patients, respectively. The median time to onset of Grade ≥3 elevation in transaminases was 8 days (range: 3 to 49), with a median duration of 7 days.

Monitor liver function tests prior to initiating ZEPZELCA, periodically during treatment, and as clinically indicated. Withhold, reduce the dose, or permanently discontinue ZEPZELCA based on severity.

Please see Important Safety Information throughout and full Prescribing Information.

Clinically meaningful duration of response (median, in months)



[a]Duration of response analysis is based on patients who responded to treatment.

Of 8 patients who had received prior immunotherapy as first- or second-line treatment[2,b]:

- Duration of response was consistent with the overall population at a **median of 5.3 months** (range: 2.8–6.4 months)[1,2,4,b]

Limitations of Data

[b]This exploratory subgroup analysis was post hoc and not powered to determine statistical significance. Results are descriptive only.

CI=confidence interval; CR=complete response; IRC=independent review committee; PR=partial response.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Extravasation Resulting in Tissue Necrosis

Extravasation of ZEPZELCA resulting in skin and soft tissue injury, including necrosis requiring debridement, can occur. Consider use of a central venous catheter to reduce the risk of extravasation, particularly in patients with limited venous access. Monitor patients for signs and symptoms of extravasation during the ZEPZELCA infusion.

If extravasation occurs, immediately discontinue the infusion, remove the infusion catheter, and monitor for signs and symptoms of tissue necrosis. The time to onset of necrosis after extravasation may vary.

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ZEPZELCA has an established safety profile

Most adverse reactions were[1,3]
GRADE 1 OR 2

- **1.9% of patients (2 of 105) permanently discontinued due to adverse reactions[1]**
  - Adverse reactions resulting in permanent discontinuation in ≥1% of patients included peripheral neuropathy and myelosuppression
- **Dose reductions due to an adverse reaction occurred in 25% of patients[1]**
  - Adverse reactions requiring dosage reductions in ≥3% of patients included neutropenia, febrile neutropenia, and fatigue
- **Dose interruptions due to an adverse reaction occurred in 30.5% of patients[1]**
  - Adverse reactions requiring dosage interruptions in ≥3% of patients included neutropenia and hypoalbuminemia

Adverse reactions (≥10%) in patients with SCLC[1]

Adverse reaction	ZEPZELCA (N=105)	
	All Grades[a,b] (%)	Grades 3–4 (%)
General disorders		
Fatigue	77	12
Pyrexia	13	0
Chest pain	10	0
Gastrointestinal disorders		
Nausea	37	0
Constipation	31	0
Vomiting	22	0
Diarrhea	20	4
Abdominal pain[c]	11	1

Adverse reactions (≥10%) in patients with SCLC[1] (cont'd)

Adverse reaction	ZEPZELCA (N=105)	
	All Grades[a,b] (%)	Grades 3–4 (%)
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[d]	33	4
Metabolism and nutrition disorders		
Decreased appetite	33	1
Respiratory, thoracic, and mediastinal disorders		
Dyspnea	31	6
Cough[e]	20	0
Infections and infestations		
Respiratory tract infection[f]	18	5
Pneumonia[g]	10	7
Nervous system disorders		
Peripheral neuropathy[h]	11	1
Headache	10	1

[a]Graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) 4.0.
[b]No grade 5 adverse reactions were reported.
[c]Includes abdominal pain, abdominal pain upper, and abdominal discomfort.
[d]Includes musculoskeletal pain, back pain, arthralgia, pain in extremity, musculoskeletal chest pain, neck pain, bone pain, and myalgia.
[e]Includes cough and productive cough.
[f]Includes upper respiratory tract infection, viral upper respiratory tract infection, respiratory tract infection, and bronchitis.
[g]Includes pneumonia and lung infection.
[h]Includes neuropathy peripheral, neuralgia, paresthesia, peripheral sensory neuropathy, hypoesthesia, and hyperesthesia.

- **Alopecia occurred in 1% of patients[3]**

SCLC=small cell lung cancer.

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Select laboratory abnormalities (≥20%) worsening from baseline[1]

Laboratory abnormalities	ZEPZELCA[a] (N=105)	
	All Grades[b] (%)	Grades 3–4 (%)
Hematology		
Decreased leukocytes	79	29
Decreased lymphocytes	79	43
Decreased hemoglobin	74	10
Decreased neutrophils	71	46
Decreased platelets	37	7
Chemistry		
Increased creatinine	69	0
Increased alanine aminotransferase	66	4
Increased glucose	52	5
Decreased albumin	32	1
Decreased sodium	31	7
Increased aspartate aminotransferase	26	2
Decreased magnesium	22	0

[a]The denominator used to calculate the rate varied from 95 to 105 based on the number of patients with a baseline value and at least one post-treatment value.
[b]Graded per NCI CTCAE 4.0.

- **In the phase 2 study, 22% of patients received granulocyte colony-stimulating factor (G-CSF) for secondary prophylaxis or therapy for neutropenia, but primary prophylaxis was not allowed[1,2]**

Please see Important Safety Information throughout and full Prescribing Information.

Minimal infusion visits—1-hour dosing, every 21 days

Recommended Dosing[1]

3.2 mg/m² by IV infusion over 60 MINUTES

Repeated EVERY 21 DAYS until disease progression or unacceptable toxicity

Initiate treatment with ZEPZELCA only if absolute neutrophil count (ANC) is at least 1,500 cells/mm^3 and platelet count is at least 100,000/mm^3.

Premedication[1]

Consider administering the following pre-infusion medications for antiemetic prophylaxis:

- Corticosteroids (dexamethasone 8 mg intravenously or equivalent)
- Serotonin antagonists (ondansetron 8 mg intravenously or equivalent)

Dose Reduction for ZEPZELCA for Adverse Reactions[1]

Dose Reduction	Total Dose
First:	2.6 mg/m² every 21 days
Second:	2 mg/m² every 21 days

Permanently discontinue ZEPZELCA in patients who are unable to tolerate 2 mg/m² or require a dose delay greater than two weeks.[1]

For full list of dosage modifications of ZEPZELCA for adverse reactions, please refer to the full Prescribing Information.

IV=intravenous; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Extravasation Resulting in Tissue Necrosis *(continued)*

Administer supportive care and consult with an appropriate medical specialist as needed for signs and symptoms of extravasation. Administer subsequent infusions at a site that was not affected by extravasation.

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CTFI ≥180 days

Actor portrayal.

Do you have a patient like Marlene, who relapsed ≥180 days following first-line platinum-based chemotherapy?

Marlene

69 years old, retired, grandmother of 4
Favorite pastime: Gardening

WHAT MATTERS TO MARLENE

"The high point of each day is when my granddaughters visit."

BACKGROUND

- Former smoker
- Diagnosed with extensive-stage SCLC

INITIAL TREATMENT

Platinum-based regimen + immunotherapy

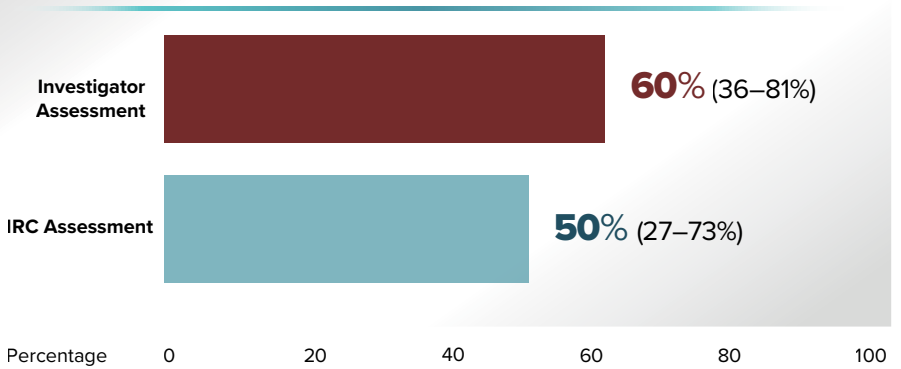
CURRENT CONDITION

- CTFI ≥180 days
- ECOG PS: 1

Please see Important Safety Information throughout and full Prescribing Information.

ZEPZELCA was studied in patients who had a CTFI of ≥180 days[3,5*†]

ORR (CR + PR) in Patients With CTFI ≥180 Days by Investigator and IRC Assessments (95% CI), n=20



DOR in the 20 patients with CTFI ≥180 days in the phase 2, single-arm study[3,5*†]:

- 5.5 (2.9–11.2) months median DOR in the investigator assessment
- 5.5 (2.8–8.5) months median DOR in the IRC assessment

***These subgroup exploratory analyses were not powered to determine statistical significance. Results are descriptive only.**

†CTFI ≥180 days=recurrence or progression 180 days or more after the last dose of platinum-based chemotherapy.

CI=confidence interval; CR=complete response; CTFI=chemotherapy-free interval; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; IRC=independent review committee; ORR=overall response rate; PR=partial response; SCLC=small cell lung cancer.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Rhabdomyolysis

Rhabdomyolysis has been reported in patients treated with ZEPZELCA.

Monitor creatine phosphokinase (CPK) prior to initiating ZEPZELCA and periodically during treatment as clinically indicated. Withhold or reduce the dose based on severity.

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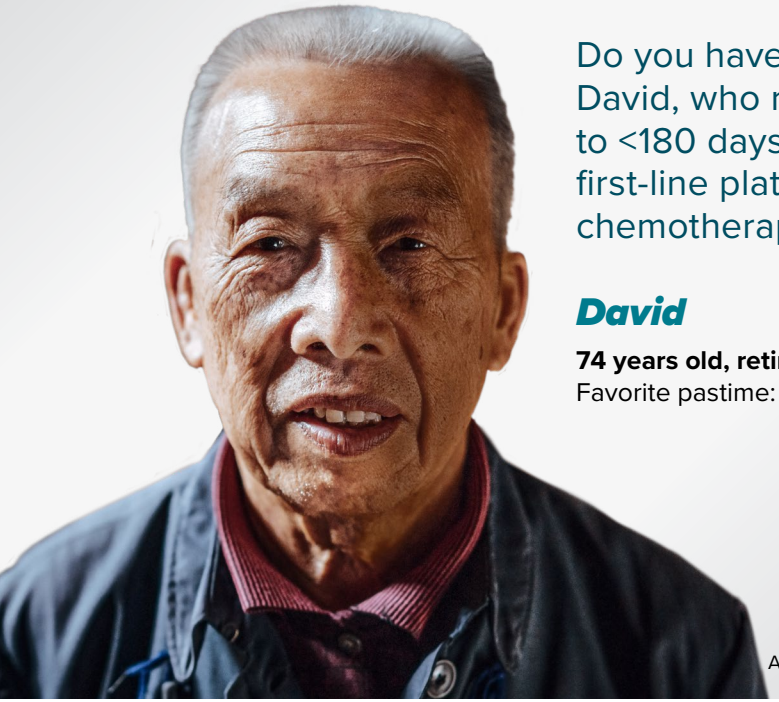
CTFI 90 to <180 days



Actor portrayal.

Do you have a patient like David, who relapsed 90 to <180 days following first-line platinum-based chemotherapy?

David

74 years old, retired shop owner
Favorite pastime: Birdwatching

WHAT MATTERS TO DAVID

"Since retiring, I stay connected with the community by volunteering at the neighborhood garden."

BACKGROUND

- Former smoker
- Diagnosed with extensive-stage SCLC

INITIAL TREATMENT

Platinum-based regimen + immunotherapy

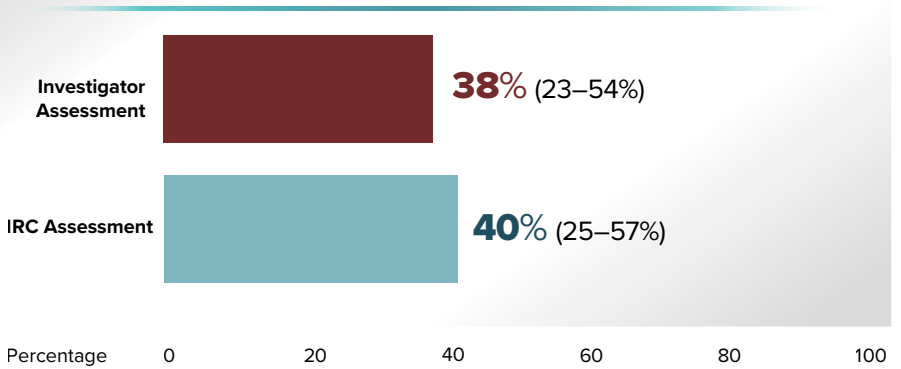
CURRENT CONDITION

- CTFI 90 to <180 days
- ECOG PS: 2

Please see Important Safety Information throughout and full Prescribing Information.

ZEPZELCA was studied in patients who had a CTFI of 90 to <180 days[3*†]

ORR (CR + PR) in Patients With CTFI 90 to <180 Days by Investigator and IRC Assessments (95% CI), n=40



DOR in the 40 patients with CTFI 90 to <180 days in the phase 2, single-arm study[3*†]:

- 6.2 (3.5–8.8) months median DOR in the investigator assessment
- 5.3 (4.9–8.8) months median DOR in the IRC assessment

***These subgroup exploratory analyses were not powered to determine statistical significance. Results are descriptive only.**

†CTFI 90 to <180 days=recurrence or progression between 90 and <180 days after the last dose of platinum-based chemotherapy.

CI=confidence interval; CR=complete response; CTFI=chemotherapy-free interval; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; IRC=independent review committee; ORR=overall response rate; PR=partial response; SCLC=small cell lung cancer.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Embryo-Fetal Toxicity

ZEPZELCA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment with ZEPZELCA and for 6 months after the last dose.

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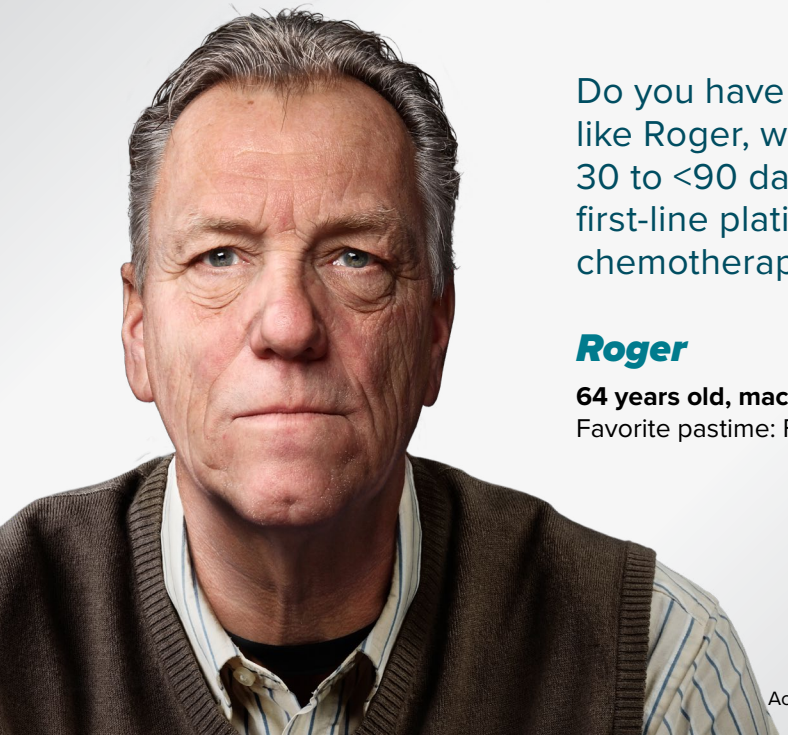
CTFI 30 to <90 days



Actor portrayal.

Do you have a patient like Roger, who relapsed 30 to <90 days following first-line platinum-based chemotherapy?

Roger

64 years old, machinist, father of 3
Favorite pastime: Fishing

WHAT MATTERS TO ROGER

"Having dinner with my wife–even after 40 years, it never gets old."

BACKGROUND

- Former smoker
- Diagnosed with extensive-stage SCLC

INITIAL TREATMENT

Platinum-based regimen

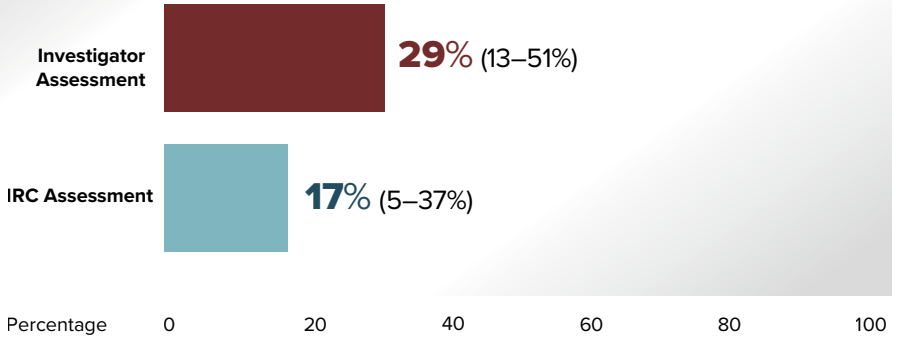
CURRENT CONDITION

- CTFI 30 to <90 days
- ECOG PS: 1

Please see Important Safety Information throughout and full Prescribing Information.

ZEPZELCA was studied in patients who had a CTFI of 30 to <90 days[3*†]

ORR (CR + PR) in Patients With CTFI 30 to <90 Days by Investigator and IRC Assessments (95% CI), n=24



DOR in the 24 patients with CTFI 30 to <90 days in the phase 2 single-arm study[3*†]:

- 4.1 (2.6–5.3) months median DOR in the investigator assessment
- 4.5 (2.4–5.3) months median DOR in the IRC assessment

***These subgroup exploratory analyses were not powered to determine statistical significance. Results are descriptive only.**

†CTFI 30 to <90 days=recurrence or progression between 30 and <90 days after the last dose of platinum-based chemotherapy.

CI=confidence interval; CR=complete response; CTFI=chemotherapy-free interval; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; IRC=independent review committee; ORR=overall response rate; PR=partial response; SCLC=small cell lung cancer.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Embryo-Fetal Toxicity *(continued)*

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ZEPZELCA and for 4 months after the last dose.

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CTFI <30 days

Do you have a patient like Louise, who relapsed <30 days following first-line platinum-based chemotherapy?

Louise

49 years old, hotel manager, mother of 2
Favorite pastime: Painting

Actor portrayal.

WHAT MATTERS TO LOUISE

"I cherish baking with my children to pass on the family traditions."

BACKGROUND

- Former smoker
- Diagnosed with extensive-stage SCLC

INITIAL TREATMENT

Platinum-based regimen + immunotherapy

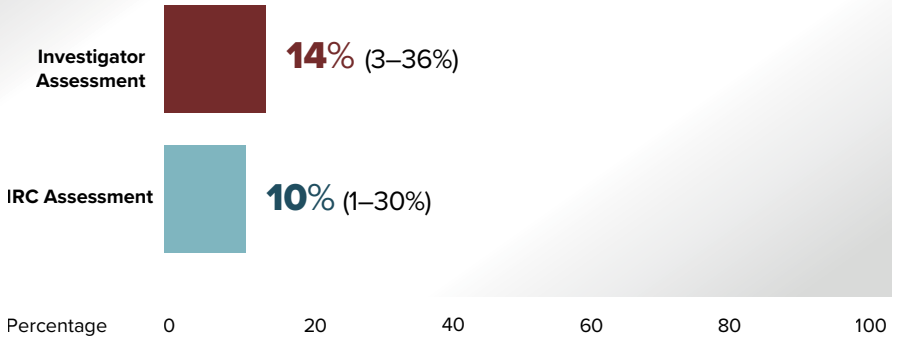
CURRENT CONDITION

- CTFI <30 days
- ECOG PS: 1

Please see Important Safety Information throughout and full Prescribing Information.

ZEPZELCA was studied in patients who had a CTFI of <30 days[3*†]

ORR (CR + PR) in Patients With CTFI <30 Days by Investigator and IRC Assessments (95% CI), n=21



DOR in the 21 patients with CTFI <30 days in the phase 2 single-arm study[3*†]:

- 7.1 (5.1–9.1) months median DOR in the investigator assessment
- 5.1 (–) months median DOR in the IRC assessment

***These subgroup exploratory analyses were not powered to determine statistical significance. Results are descriptive only.**

†CTFI <30 days=recurrence or progression in <30 days after the last dose of platinum-based chemotherapy.

CI=confidence interval; CR=complete response; CTFI=chemotherapy-free interval; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; IRC=independent review committee; ORR=overall response rate; PR=partial response; SCLC=small cell lung cancer.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

Lactation

There are no data on the presence of ZEPZELCA in human milk, however, because of the potential for serious adverse reactions from ZEPZELCA in breastfed children, advise women not to breastfeed during treatment with ZEPZELCA and for 2 weeks after the last dose.

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2025 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®):

Lurbinectedin (ZEPZELCA®) is preferred when CTFI ≤6 months and recommended when CTFI >6 months[6]

National Comprehensive Cancer Network® (NCCN®) guidance for lurbinectedin (ZEPZELCA) as a subsequent SCLC therapy option (ECOG PS 0–2)[6*†]

NCCN CATEGORY 2A RECOMMENDATION

CTFI ≤6 months	CTFI >6 months
PREFERRED REGIMEN‡	***RECOMMENDED REGIMEN§***

Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.

*Subsequent systemic therapy refers to second-line and beyond therapy.[6]
†See the NCCN Guidelines® for SCLC for detailed recommendations, including other treatment options.
‡Preferred interventions are based on superior efficacy, safety, and evidence, and, when appropriate, affordability.[6]
§Other recommended interventions may be somewhat less efficacious, more toxic, or based on less mature data, or are significantly less affordable for similar outcomes.[6]

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

References: 1. ZEPZELCA (lurbinectedin) Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc. **2.** Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncol.* 2020;21(5):645–654. **3.** Data on file-LUR-2020-003. Jazz Pharmaceuticals, Inc. **4.** Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial [supplementary appendix]. *Lancet Oncol.* 2020;21(5):645–654. **5.** Subbiah V, Paz-Ares L, Besse B, et al. Antitumor activity of lurbinectedin in second-line small cell lung cancer patients who are candidates for re-challenge with the first-line treatment. *Lung Cancer.* 2020;150:90–96. **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer. V.2.2025. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed September 5, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. **7.** Data on file-REF-17819. Jazz Pharmaceuticals, Inc. **8.** Data on file-REF-18136. Jazz Pharmaceuticals, Inc.

CTFI=chemotherapy-free interval; ECOG PS=Eastern Cooperative Oncology Group Performance Status; NCCN=National Comprehensive Cancer Network® (NCCN®); SCLC=small cell lung cancer.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions, including laboratory abnormalities, (≥20%) are leukopenia (79%), lymphopenia (79%), fatigue (77%), anemia (74%), neutropenia (71%), increased creatinine (69%), increased alanine aminotransferase (66%), increased glucose (52%), thrombocytopenia (37%), nausea (37%), decreased appetite (33%), musculoskeletal pain (33%), decreased albumin (32%), constipation (31%), dyspnea (31%), decreased sodium (31%), increased aspartate aminotransferase (26%), vomiting (22%), decreased magnesium (22%), cough (20%), and diarrhea (20%).

Please see Important Safety Information throughout and full Prescribing Information.

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

DRUG INTERACTIONS

Effect of CYP3A Inhibitors and Inducers

Avoid coadministration with a strong or a moderate CYP3A inhibitor (including grapefruit and Seville oranges) as this increases lurbinectedin systemic exposure which may increase the incidence and severity of adverse reactions to ZEPZELCA. If coadministration cannot be avoided, reduce the ZEPZELCA dose as appropriate.

Avoid coadministration with a strong CYP3A inducer as it may decrease systemic exposure to lurbinectedin, which may decrease the efficacy of ZEPZELCA.

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ZEPZELCA offers an established, second-line treatment option in mSCLC

>5 YEARS OF EXPERIENCE

ZEPZELCA has over 5 years of experience in the clinical practice setting[1]

#1Rx

ZEPZELCA is the #1-prescribed medication in the second-line treatment of SCLC* following first-line platinum-based therapies[7]

>30k ADULT PATIENTS TREATED

Over 30,000 adult patients treated with ZEPZELCA to date in the United States[8]

For your adult patients with mSCLC with disease progression on or after platinum-based therapy,

EXPLORE ZEPZELCA

IMPORTANT SAFETY INFORMATION *(CONTINUED)*

GERIATRIC USE

Of the 105 patients with SCLC administered ZEPZELCA in clinical studies, 37 (35%) patients were 65 years of age and older, while 9 (9%) patients were 75 years of age and older. No overall difference in effectiveness was observed between patients aged 65 and older and younger patients.

There was a higher incidence of serious adverse reactions in patients ≥65 years of age than in patients <65 years of age (49% vs 26%, respectively). The serious adverse reactions most frequently reported in patients ≥65 years of age were related to myelosuppression and consisted of febrile neutropenia (11%), neutropenia (11%), thrombocytopenia (8%), and anemia (8%).

mSCLC=metastatic small cell lung cancer; SCLC=small cell lung cancer.

Total number of patients treated is determined as total vials sold divided by 7.46 (average vials per patient) based on SHS claims data from July 2020–April 2025.[8]

*Source: Symphony Health Solutions (SHS) claims data: July 2020–June 2024.

Please see Important Safety Information throughout and full Prescribing Information.

Jazz Pharmaceuticals

Pharma Mar