AN IMPORTANT UPDATE TO THE NCCN GUIDELINES®
FOR SMALL CELL LUNG CANCER (SCLC)

ZEPZELCA™ (lurbinectedin) for injection 4 mg

INDICATION

ZEPZELCA™ (lurbinectedin) is indicated for the treatment of adult patients with metastatic 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).

For subsequent SCLC treatment, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) now recommend lurbinectedin (ZEPZELCA) as an option for patients who relapse **≤6 months** *or* **>6 months*** following first-line platinum-based chemotherapy.[1†‡]

NCCN recommendations for lurbinectedin (ZEPZELCA) as a subsequent SCLC therapy option[1†]

	Relapse ≤6 months ECOG PS 0–2	Relapse >6 months*
Category 2A recommended	✓	✓

- Lurbinectedin (ZEPZELCA) is also recommended as a **preferred treatment option**† for patients who relapse ≤6 months with ECOG PS 0–2[1]

ECOG PS=Eastern Cooperative Oncology Group Performance Status.
Category 2A: Based on lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[1]
*Other recommended regimen.
†See the NCCN Guidelines for SCLC for detailed recommendations, including other treatment options.
‡Subsequent refers to second-line and beyond therapy.
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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.

Administer ZEPZELCA only to patients with baseline neutrophil count of at least 1,500 cells/mm^3 and platelet count of at least 100,000/mm^3.

Monitor blood counts including neutrophil count and platelet count prior to each administration. For neutrophil count less than 500 cells/mm^3 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.

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.

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.

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

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 final dose.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions, including laboratory abnormalities, (≥20%) are leukopenia, lymphopenia, fatigue, anemia, neutropenia, increased creatinine, increased alanine aminotransferase, increased glucose, thrombocytopenia, nausea, decreased appetite, musculoskeletal pain, decreased albumin, constipation, dyspnea, decreased sodium, increased aspartate aminotransferase, vomiting, cough, decreased magnesium, and diarrhea.

Please see accompanying full Prescribing Information.

SEE THE EFFICACY AND SAFETY DATA AT **ZEPZELCApro.com**

Reference: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Cell Lung Cancer. V.1.2021. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed August 11, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org.

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