MEET THE EXPERTS

ISSUE 7 SMALL CELL LUNG CANCER

FEATURING

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INSIDE THIS ISSUE:

- Recognizing and responding to relapse in patients with small cell lung cancer (SCLC)
- Efficacy, tolerability, and safety considerations for treatment selection
- Helping your patients to stay on treatment with dose modifications and convenient dosing

> *"In order to catch relapse early, you need to dig in deep; really listen to what your patients are telling you and what their scans are showing you."*
>
> —Jo-Ellen Woodruff, APRN-CNP

MANAGING PATIENT CARE

AFTER RELAPSE IN SMALL CELL LUNG CANCER

*Dr Smith and Ms Woodruff are paid consultants of Jazz Pharmaceuticals. This content is intended for informational purposes only and is not a substitute for your clinical knowledge or professional judgment. The views and opinions expressed in this article are those of the authors and Jazz Pharmaceuticals and do not necessarily reflect the opinions of The Arthur G. James Cancer Hospital at The Ohio State University Wexner Medical Center, and are not an endorsement of Jazz Pharmaceuticals or any of their products.

A LOOK AT **PATIENT CONSIDERATIONS** AND **TREATMENT STRATEGIES** AFTER RELAPSE

Q. What challenges with small cell lung cancer (SCLC) are most common in your practice?

MS. The biggest challenge is the fact that we know the stated goal of treatment is not to achieve a cure. ES-SCLC is an incurable disease, so everything we do is technically to palliate their symptoms.[1] We are certainly trying to prolong their life—and I'm confident that we accomplish that goal most of the time with the medications that we give—but we also need to make sure that we are keeping their quality of life in mind and making sure that the time they have is as good as it can be.

JW. Yes, and their comorbidities can always be a challenge for that. With this disease, COPD is common, and many of them will have cardiac issues like hypertension, coronary artery disease, or previous MIs. Some of them have chronic pain prior to the cancer as well, or they may be diabetic.[2,3] We are experts on cancer treatment, so we can help bridge other issues that come up, but we also rely heavily on their primary care physician to help manage those things. It is the same thing with pain management—if it's severe, we want to involve palliative medicine early.

Q. In your experience, how do SCLC patients present when they've relapsed?

JW. It really is case-by-case, but oftentimes, we'll see patients relapse where they had cancer before. We commonly see metastases in the brain, too, but it could really be anywhere.[3] Our patients often feel well but with routine imaging, you will find they've already relapsed. Other times they come in because they are symptomatic, or they've ended up in the hospital, and their labs indicate a problem.

MS. I would add that the majority of our patients still look well enough, even after their SCLC has progressed, that they are eligible for a second-line treatment option.

Q. How many of your patients with SCLC require a second-line treatment option?

JW. In my clinical practice, almost all of our patients go to second-line therapy—more than 90%, or probably even 95%. But it's always a decision with the patient as to what they will do next.

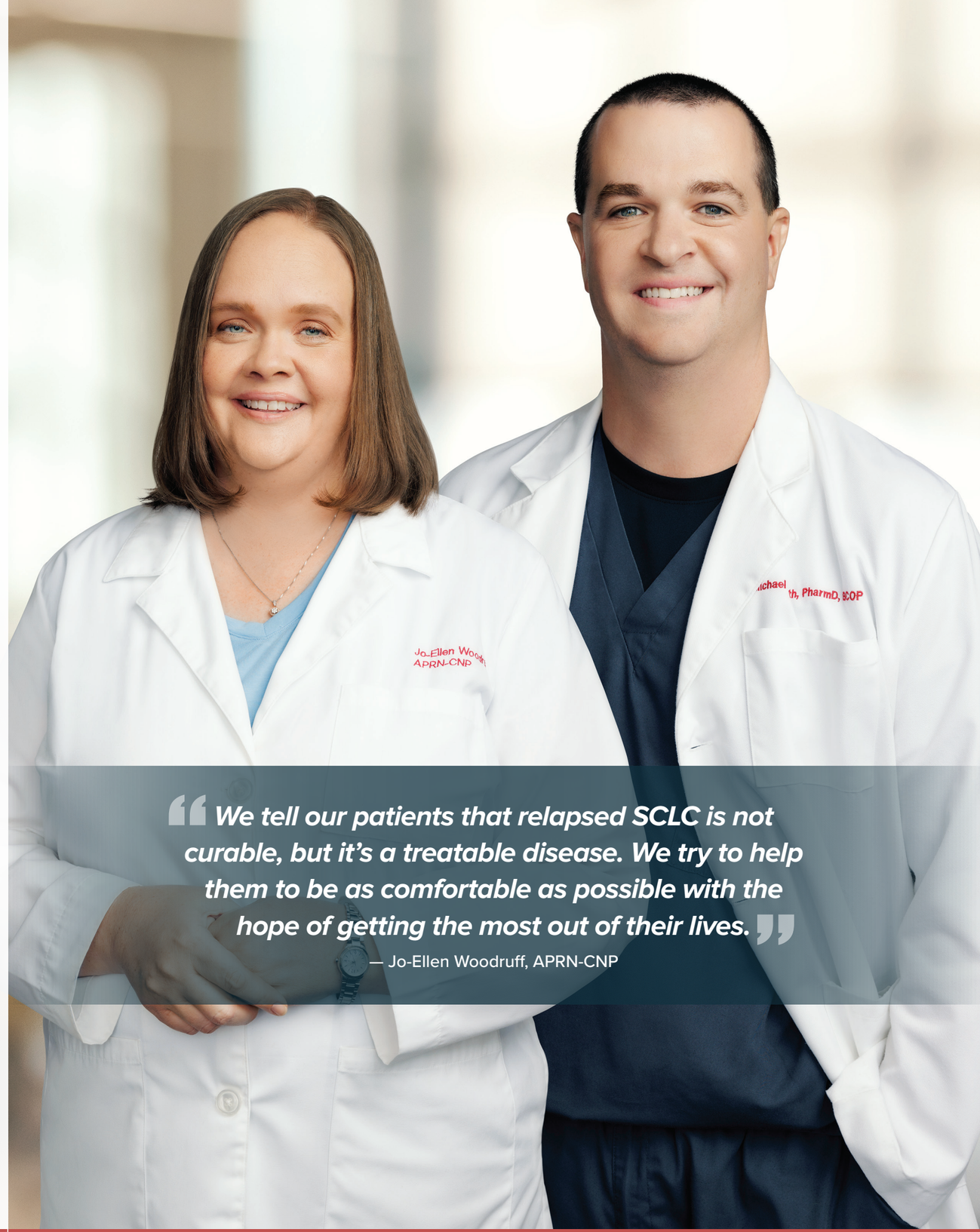
MS. If they are eligible based on their performance status and other comorbidities, then, yes, the majority of patients we see will go on to a second-line therapy. The nature of small cell lung cancer is that our first-line treatment options tend to work well, but whether they're platinum responsive or platinum resistant, SCLC virtually always comes back and progresses, so most patients do need a second-line option.[3,4]

Q. What is your #1 piece of advice to other practitioners working with patients with SCLC?

MS. To me, balancing treatment goals is the most important thing: balancing treating the patient, managing their cancer, and also ensuring they're still living with a good quality of life.[3,5] Knowing the goal of your treatment and communicating that clearly to the patient when you're talking about risks and benefits, doses, supportive care, etc are paramount.

JW. My biggest things are to listen to the patient and to treat the patient in the moment. We know relapse is going to happen at some point—that's always the biggest concern with this patient population—so if they're telling you one of their symptoms is getting worse, most likely it's time to get imaging and see what's going on.[3] It's important to listen to what the patient is telling you: how they're feeling, what is going on, and what they want in their lives, so that you're treating the patient and not just the disease.

COPD=chronic obstructive pulmonary disease; ES-SCLC=extensive-stage small cell lung cancer; MI=myocardial infarction.



"We tell our patients that relapsed SCLC is not curable, but it's a treatable disease. We try to help them to be as comfortable as possible with the hope of getting the most out of their lives."

— Jo-Ellen Woodruff, APRN-CNP

CLINICAL EXPERIENCE: SECOND-LINE TREATMENT FOR SCLC WITH ZEPZELCA® (lurbinectedin)

Q. How important is starting treatment quickly with your patients who have relapsed?

JW. It's not a disease you can sit on for a long time. If they have a recurrence, it's just going to get worse, and it's going to get worse quickly.[5] In general, it's a disease that we want to treat urgently.[6]

MS. There is certainly an urgency to it; patients who have relapsed small cell lung cancer commonly don't feel well. They often have difficulty breathing; they might need to be on oxygen, etc, so getting a response—especially in the relapsed setting—is important for them.[7]

Q. What has been your experience when treating patients with a second-line treatment like ZEPZELCA?

MS. What is shown in the clinical trial is what we have seen in patients. In the phase 2 trial, adults with metastatic SCLC with disease progression on or after platinum-based chemotherapy had an overall response rate (ORR) of 35% by investigator assessment (IA) and 30% by an independent review committee (IRC). That's greater than 1 in 3 patients by investigator assessment, which is notable in my experience in the relapse setting. The median duration of response (DoR) was 5.3 months by IA and 5.1 months by IRC.[8]

Study Design

The phase 2 trial was a multicenter, open-label, multi-cohort trial evaluating ZEPZELCA as a single agent in 105 adult patients with advanced or metastatic SCLC with disease progression on or after platinum-based chemotherapy. Patients received ZEPZELCA 3.2 mg/m^2 by intravenous infusion every 21 days (1 cycle) for a median of 4 cycles (range: 1 to 24 cycles). The median age was 60 years (range: 40 to 83 years). Baseline ECOG PS was 0 or 1 in 92% of patients. The primary efficacy outcome was confirmed ORR by IA. Additional ranked efficacy outcome measures included DoR and an IRC-assessed ORR using RECIST version 1.1.[8]

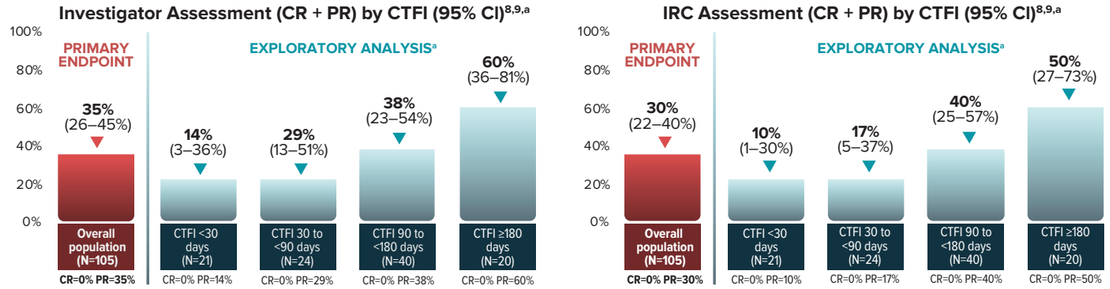
ECOG PS=Eastern Cooperative Oncology Group Performance Status; RECIST=Response Evaluation Criteria in Solid Tumors.

INDICATION

ZEPZELCA® (lurbinectedin) for injection 4 mg, 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).

OVERALL RESPONSE RATE WAS EVALUATED IN BOTH PLATINUM-RESISTANT AND PLATINUM-SENSITIVE SUBGROUPS



[a]**Limitations of Data:** This exploratory subgroup analysis was not powered to determine statistical significance. Results are descriptive only.

CR=complete response; CI=confidence interval; CTFI=chemotherapy-free interval; IRC=independent review committee; PR=partial response.

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>
> — Michael Smith, PharmD, BCOP

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.

ZEPZELCA® (lurbinectedin) for injection 4 mg

Please see pages 10-11 for Important Safety Information and CLICK HERE for full Prescribing Information.

CLINICAL EXPERIENCE: SECOND-LINE TREATMENT FOR SCLC WITH ZEPZELCA® (lurbinectedin)

> ***"Its tolerability profile is one of the factors that makes ZEPZELCA an intriguing choice in the relapsed setting."***
>
> — Michael Smith, PharmD, BCOP

Q. What do your experience and the safety results from the clinical trial tell you about ZEPZELCA?

JW. The side effect profile of ZEPZELCA stands out to me. What we've seen matches the clinical trial: different patients can have different experiences of course, but most of our patients have done really well with it.[8,10] They'll say, "No, this wasn't too bad," when they come in. They're able to do the things that they want to do. I think that's great; that's a positive for the patient.

We also teach our patients about any expected side effects, specifically how to recognize early signs of adverse events and to call us. We tell our patients, "Call us if you're more symptomatic, such as a cut that can't stop bleeding, or if you're tired in a way that feels unusual."[8] We're able to manage many side effects over the phone. We get a lot of calls to the office; if they say something's wrong, I'll bring them in sooner for a visit and see what's going on.

MS. In a disease like relapsed SCLC, if the drug is working, we want to keep them on it. But if keeping them on it is harming them, that's a problem. Keeping patients on ZEPZELCA usually isn't a problem in my experience. We're able to manage most side effects. For example, the most common side effect is myelosuppression, which patients are already used to us monitoring from their experience with platinum-containing chemotherapies.[8,11] It's a toxicity that can be managed as long as it is closely monitored. We don't always give primary prophylaxis with growth factor support, but it's a consideration if we think a patient will struggle based on their history.[8] On the other hand, our typical recommendation is to premedicate with an antiemetic like a 5-HT3 antagonist and/or a corticosteroid.[8]

5-HT3=5-hydroxytryptamine type 3.

Permanent discontinuation due to an adverse reaction occurred in 1.9% of patients with SCLC (2 of 105).[8]

- Adverse reactions resulting in permanent discontinuation in ≥1% of patients included peripheral neuropathy and myelosuppression

Dosage reductions due to an adverse reaction occurred in 25% of patients.[8]

- Adverse reactions requiring dosage reductions in ≥3% of patients included neutropenia, febrile neutropenia, and fatigue

Dosage interruptions due to an adverse reaction occurred in 30.5% of patients.[8]

- Adverse reactions requiring dosage interruption in ≥3% of patients included neutropenia and hypoalbuminemia

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.

Most adverse reactions were Grade 1 or 2[8]

ADVERSE REACTIONS (≥10%) IN PATIENTS WITH SCLC WHO RECEIVED ZEPZELCA® (lurbinectedin)[8]

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
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

- Alopecia occurred in 1% of patients.[9]

[a]Graded per National Cancer Institute Common Terminology Criteria for Adverse Events v4.0.
[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.

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.

ZEPZELCA® (lurbinectedin) for injection 4 mg

CLINICAL EXPERIENCE: SECOND-LINE TREATMENT FOR SCLC WITH ZEPZELCA® (lurbinectedin)

Q. How does the dosing structure of ZEPZELCA impact your patients?

JW. While the recommended starting dose for ZEPZELCA is 3.2 mg/m^2, the option to modify the dosing can be helpful for patients who need it.[8] There's no point to giving patients a treatment if they are having AEs and can't tolerate it, but we can choose to keep a patient on therapy longer and to give them a different dose. In my experience, many patients who are dose reduced find the new dose to be more tolerable.

MS. Agreed. We want patients to stay on treatment longer, especially if they tend to tolerate ZEPZELCA at a lower dose. There are multiple dose reduction manipulations that you can do to get on top of any adverse events.[8] Sometimes, when a patient is struggling, we have a discussion up-front with the patient about monitoring and dose reductions: "Dose reductions can help you to continue treatment, so they're not a bad thing or a failure." The goal is to keep patients on therapy as long as it's working for them and they're able to tolerate it.

Q. How does ease of administration and timing impact how you and your patients consider treatment?

MS. The dosing schedule can be impactful for patients. One infusion for 1 hour every 21 days is a great option.[8] You don't know how much time they have left, so for patients, it can make planning life easier if they don't have to come in for an infusion as often. In my experience, when you have this medication every 21 days, generally our patients can find a cadence to how they'll feel. That pattern of symptoms makes it easier for patients to predict when they could feel effects.

> ***"Patients are often able to tolerate ZEPZELCA—sometimes with a dose reduction, sometimes not. We want our patients to stay on treatment and to benefit from it."***
>
> — Michael Smith, PharmD, BCOP

A STRAIGHTFORWARD DOSE-REDUCTION SCHEDULE TO HELP MANAGE ADVERSE REACTIONS[8]

Recommended starting dose	First dose reduction	Second dose reduction
3.2 mg/m^2 every 21 days or until disease progression or unacceptable toxicity	2.6 mg/m^2 every 21 days*	2 mg/m^2 every 21 days*

*Please refer to the full Prescribing Information for specific adverse event-related dose modifications.

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.

Permanently discontinue ZEPZELCA in patients who are unable to tolerate 2 mg/m^2 or require a dose delay greater than 2 weeks.[8]

IMPORTANT SAFETY INFORMATION (continued)

Extravasation Resulting in Tissue Necrosis (continued)

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.

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.

> ***"We want our patients to stay on treatment for as long as they can and to feel as good as possible. Managing side effects is very important to our patients."***
>
> — Michael Smith, PharmD, BCOP

RECOMMENDED DOSAGE OF ZEPZELCA® (lurbinectedin)[8]

ZEPZELCA for injection	60-minute IV infusions	Administered every 3 weeks
3.2 mg/m^2	**60 minutes**	**21 days** Until disease progression or unacceptable toxicity

Initiate treatment with ZEPZELCA only if absolute neutrophil count is ≥1,500 cells/mm^3 and platelet count is ≥100,000/mm^3.[8]

Premedication[8]

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

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

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.

ZEPZELCA® (lurbinectedin) for injection 4 mg

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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. 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.

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.

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%).

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.

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%)

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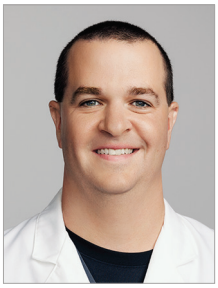
ZEPZELCA® (lurbinectedin) for injection 4 mg

"We want to set our patients up for success. When they relapse, it's important to have a second-line treatment option like ZEPZELCA that can balance reduction of the disease burden with tolerability."

— Michael Smith, PharmD, BCOP

LEARN MORE ABOUT A SECOND-LINE OPTION FOR YOUR PATIENTS WITH RELAPSED SCLC AT

ZEPZELCAPRO.COM



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Dr Smith earned his doctorate in pharmacy from The Ohio State University College of Pharmacy. He completed a pharmacy practice residency at The Ohio State University Wexner Medical Center and an oncology pharmacy residency at The Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University Wexner Medical Center, where he also serves as a PGY2 Oncology Pharmacy Residency Preceptor.

Dr Smith has given numerous lectures and presentations on oncology and is a member of the Hematology/Oncology Pharmacy Association.

Jo-Ellen C. Woodruff, APRN-CNP, is an acute care nurse practitioner in the Division of Medical Oncology at The Ohio State University Comprehensive Cancer Center—The James Cancer Hospital and Richard J. Solove Research Institute in Columbus, Ohio. She received a Bachelor of Science in Nursing and Master of Science in Adult Health Nursing from The Ohio State University and a Master of Science in Nursing with an Acute Care Nurse Practitioner concentration (cardiac subspecialty) from Wright State University in Dayton, Ohio. She has over 20 years of medical experience and, most recently, 13 years in thoracic oncology.

Ms Woodruff is a member of the Oncology Nursing Society and the Ohio Association of Advanced Practice Nurses.

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