



NDA 213702/S-013

**SUPPLEMENT APPROVAL/
RELEASE FROM POSTMARKETING REQUIREMENT**

Jazz Pharmaceuticals Ireland, Ltd.
c/o Jazz Pharmaceuticals, Inc.
Attention: Sushma Iyengar, PhD
Senior Director, Regulatory Affairs
One Commerce Square
2005 Market Street, Suite 2100
Philadelphia, PA 19103

Dear Dr. Iyengar:

Please refer to your supplemental new drug application (sNDA) dated August 27, 2026, received August 27, 2026, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Zepzelca (lurbinectedin) intravenous infusion.

This Prior Approval sNDA provides for the voluntary withdrawal of the accelerated approval indication associated with postmarketing requirement (PMR) 3831-7: lurbinectedin for the treatment of adult patients with metastatic small-cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

You requested withdrawal of approval of this indication and waived the expedited withdrawal procedures set forth in section 506(c)(3) of the Food, Drug, and Cosmetic Act, as amended by the Food and Drug Omnibus Reform Act of 2022. You would have to obtain FDA approval of an efficacy supplement in order to resume marketing the product for this indication.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

RELEASE FROM POSTMARKETING REQUIREMENT

We have received your submission dated August 27, 2026, related to the following postmarketing requirement listed in our October 24, 2022, postapproval postmarketing requirement letter:

- 3831-7 Conduct a clinical trial investigating lurbinectedin in patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy to verify the clinical benefit of lurbinectedin for the treatment of metastatic SCLC. The primary endpoint

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

should be overall survival. Tumor-related secondary endpoints, including progression free survival, should be determined by an Independent Review Committee.

Final Protocol Submission:	03/2022 (completed)
Interim Report Submission:	11/2024
Trial Completion:	06/2025
Final Report Submission:	12/2025

We have reviewed your submission and have determined that you are released from the above requirement as it is no longer needed because of your voluntary withdrawal of the indication for the treatment of metastatic SCLC with disease progression on or after platinum-based chemotherapy.

This closes all of your postmarketing requirements and postmarketing commitments acknowledged in our October 24, 2022, letter. You are not required to report on the status of closed (released or fulfilled) PMRs/PMC in your annual report required under 21 CFR 314.81(b)(2)(vii).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.³ Information and Instructions for completing the form can be found at FDA.gov.⁴

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

³ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Jeffrey Ingalls, Senior Regulatory Health Project Manager, at 301-796-4444 or via email at Jeffrey.Ingalls@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Erin Larkins, MD
Director
Division of Oncology 2
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ERIN A LARKINS
09/30/2026 10:08:56 AM