

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

218711Orig1s000

Trade Name: Beizray injection

Generic or Proper Name: docetaxel

Sponsor: Zhuhai Beihai Biotech Co., Ltd.

Approval Date: October 23, 2024

Indication: Beizray (docetaxel) injection is indicated for:

- Breast Cancer (BC): single agent for locally advanced or metastatic BC after failure of prior chemotherapy; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC.
- Non-small Cell Lung Cancer (NSCLC): single agent is indicated for locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC.
- Prostate Cancer: with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.
- Gastric Adenocarcinoma: with cisplatin and fluorouracil for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease.
- Squamous Cell Carcinoma of the Head and Neck (SCCHN): with cisplatin and fluorouracil for the induction treatment of patients with locally advanced SCCHN.

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APPROVAL LETTER



NDA 218711

NDA APPROVAL

Zhuhai Beihai Biotech Co., Ltd.
Attention: Tong Le
US Agent for Zhuhai Beihai Biotech Co., Ltd.
Conjugation Healthcare
62E Shrewsbury Place
Princeton, NJ 08540

Dear Tong Le:

Please refer to your new drug application (NDA) dated October 6, 2023, received October 6, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Beizray (docetaxel) injection.

We acknowledge receipt of your major amendment dated May 17, 2024, which extended the goal date by three months.

This NDA provides for the use of Beizray (docetaxel) injection for the following:

- Breast Cancer:
 - Docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy.
- Non-small Cell Lung Cancer:
 - Docetaxel as a single agent is indicated for the treatment of patients with locally advanced or metastatic nonsmall cell lung cancer after failure of prior platinum-based chemotherapy.
- Prostate Cancer:
 - Docetaxel in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer.
- Gastric Adenocarcinoma:
 - Docetaxel in combination with cisplatin and fluorouracil is indicated for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease.

- Head and Neck Cancer:
 - Docetaxel in combination with cisplatin and fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN).

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 218711.**” Approval of this submission by FDA is not required before the labeling is used.

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>.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Beizray (docetaxel) injection shall be 24 months from the date of manufacture when stored at Store at 20°C to 25°C (68°F to 77°F). Excursions permitted from 15°C to 30°C (59°F to 86°F). [see USP controlled room temperature]. The expiration date on the carton labeling for the co-packaged product, Beizray and Albumin shall be dependent on the shortest or earliest expiration date of any component.

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 none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

REPORTING REQUIREMENTS

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

³ For the most recent version of a guidance, check the FDA guidance web page at

<https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). The FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website⁶.

If you have any questions, contact Christal Lee, Regulatory Project Manager, at 240-402-2711 or Christal.Lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Christy Osgood, MD
Supervisory Associate Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
- Carton and Container Labeling
- Kit (Tray/Blister Pack) Labeling

⁶ <https://www.uspnf.com/>

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/

CHRISTY L OSGOOD
10/23/2024 12:10:53 PM