NDA 211109/S-009

SUPPLEMENT APPROVAL

Tetraphase Pharmaceuticals Inc.
Attention: Marie Minassian
Senior Director, Regulatory Operations
35 Gatehouse Drive
Waltham, MA 02451

Dear Marie Minassian:

Please refer to your supplemental new drug application (sNDA) dated and received January 12, 2024, and your amendments dated January 22, 2024, October 2, 2024, and October 21, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xerava (eravacycline) for injection.

This Prior Approval sNDA provides for the following updates to the prescribing information (PI):

In the **HIGHLIGHTS OF PRESCRIBING INFORMATION**:

- Information under the headings: **RECENT MAJOR CHANGES**, **DOSAGE AND ADMINISTRATION**, **WARNINGS AND PRECAUTIONS**, and **DRUG INTERACTIONS** was updated to align with changes made to the full prescribing information (FPI); under the **ADVERSE REACTIONS** heading the adverse reporting phone number was updated.

In the Full Prescribing Information updates were made:

- In section **2 DOSAGE AND ADMINISTRATION**, **subsection 2.4** Preparation and Administration, storage information for the diluted solutions was updated.

- In section **7 DRUG INTERACTIONS, subsection 7.1** Effect of Other Drugs on XERAVA, the impact of P-gp and OATP1B1/B3 transporters was removed.

- In section **11 DESCRIPTION** the numbers in the molecular formula were subscripted. Sodium content information for the reconstituted XERAVA solution was included.

- In section **12 CLINICAL PHARMACOLOGY**, **subsection 12.3** Pharmacokinetics, updates were made to add information on eravacycline

as a substrate for P-gp and organic anion transporter peptide OATP1B1 and OATP1B3.

- In section **17 Patient Counseling Information**, updated the required regulatory statement to align with the verbatim statement in 21 CFR 201.24 (d).

- Minor editorial and formatting revisions were made throughout the labeling.

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.

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 (Prescribing Information), 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 the 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).

[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.

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 *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 211109/S-009**." Approval of this submission by FDA is not required before the labeling is used.

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, please contact Jennifer Grant, MSHS, Regulatory Project Manager, at jennifer.grant@fda.hhs.gov or (301) 796-0480.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

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/

DMITRI IARIKOV
12/13/2024 03:32:04 PM