NDA 212887/S-9
NDA 212887/S-10

**SUPPLEMENT APPROVALS**
**FULFILLMENT OF POSTMARKETING REQUIREMENTS**

ViiV Healthcare Company
Attention: Mark M. Pace
Associate Director, Global Regulatory Affairs
410 Blackwell Street
Durham, NC 27701

Dear Mark Pace:

Please refer to your supplemental new drug applications (sNDAs) dated and received March 21, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vocabria (cabotegravir) tablet.

These Prior Approval supplemental new drug applications (sNDAs) provide for the following changes to the labeling:

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- To update labeling with the additional data from pediatric patients enrolled in the HIV-1 treatment study, 208580 (MOCHA).
- To remove the neural tube defect information from USE IN SPECIFIC POPULATIONS, Pregnancy

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- To update the labeling with additional data from pediatric patients who were enrolled in HIV-1 pre-exposure prophylaxis studies HPTN-083-01 and HPTN-084-01

## APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

Vocabria (cabotegravir) is approved in combination with Edurant (rilpivirine) for short-term treatment of HIV-1 infection in adolescents 12 years of age and older and weighing at least 35 kg who are virologically suppressed (HIV 1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or

suspected resistance to either cabotegravir or rilpivirine. NDA 212887, supplement 9 provides for pediatric information pursuant to both the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Act (PREA). This approval is in response to both a written request and a PREA PMR.

## WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

## 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 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 these supplemental applications, 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

[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.

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.

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We note that you have fulfilled the pediatric study requirements for the ages 12 to less than 18 years of age, weighing at least 35 kg,

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

## FULFILLMENT OF POSTMARKETING REQUIREMENT

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We have received your submission dated March 21, 2024, containing the final report for the following postmarketing requirements listed in the January 21, 2021 approval letter and the August 15, 2022 postapproval postmarketing requirement letter.

3997-1 Conduct a study in subjects weighing 35 kg and higher (approximately 12 to less than 18 years of age) who are HIV-1 infected, virologically suppressed (HIV-1 RNA <50 copies/mL) and on a stable antiretroviral regimen at the time of enrollment, to assess the pharmacokinetics, tolerability, and short-term safety of VOCABRIA after 4-week administration in combination with other antiretroviral drug(s).

4223-5 Conduct a study in subjects weighing 35 kg and higher (approximately 12 to less than 18 years of age) who are HIV-1 infected, virologically suppressed (HIV-1 RNA <50 copies/mL) and on a stable antiretroviral regimen at the time of enrollment, to assess the pharmacokinetics, tolerability, and short-term safety of VOCABRIA after 4-week administration in combination with other antiretroviral drug(s).

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that there are postmarketing requirements listed in the January 21, 2021, approval letter and the August 15, 2022, postapproval postmarketing requirement letter that are still open.

## 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]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

## 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).

[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

If you have any questions, contact Raina Pandya, Regulatory Project Manager, at (240) 402-3941.

Sincerely,

*{See appended electronic signature page}*

Wendy Carter, DO
Director (Acting)
Division of Antivirals
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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**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.**

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/s/

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