February 5th ,2025

The NDA number in the table under the row NDA/BLA # and Supplement # was incorrectly entered as 201853 instead of the correct NDA number of 208351. This has been changed in the review correction document dated February 5, 2025.

Date	February 3, 2025
From	Glen Huang, DO (Clinical Reviewer) Stephanie Troy, MD (CDTL) Yodit Belew, MD (ADTL)
Subject	Combined Clinical, Cross Discipline Team Leader and Division Director Review
Application Type	Prior Approval Efficacy Supplement
NDA/BLA # and Supplement#	NDA 201853 S-14 S-15
Applicant	Gilead
Date of Submission	April 19, 2024
PDUFA Goal Date	February 19, 2025
Proprietary Name	ODEFSEY
Established or Proper Name	Emtricitabine/rilpivirine/tenofovir alafenamide (FTC/RPV/TAF)
Dosage Form(s)	Fixed-dose combination tablet
Applicant Proposed Indication(s)/Population(s)	Expansion of current indication to pediatric patients weighing at least 25kg
Applicant Proposed Dosing Regimen(s)	One tablet (FTC 200 mg, RPV 25 mg, and TAF 25 mg) orally once daily with a meal
Recommendation on Regulatory Action	Approval of this supplement
Recommended Indication(s)/Population(s)	Complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing at least 25kg as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL; or to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of ODEFSEY.
Recommended Dosing Regimen	One tablet (FTC 200 mg, RPV 25 mg, and TAF 25 mg) orally once daily with a meal

Introduction

The Applicant submitted an efficacy supplement to seek approval of ODEFSEY for pediatric patients weighing at least 25kg. This supplement is also to seek fulfillment of the Pediatric Research Equality Act (PREA) postmarketing requirement (PMR) 3043-1, issued in the March 1, 2016, approval letter which states:

> Using data from agreed upon studies of the component products, conduct and submit an assessment of safety, pharmacokinetics, and antiviral activity of Odefsey (emtricitabine,

rilpivirine, and tenofovir alafenamide) in pediatric patients 6 years to less than 12 years of age OR greater than 25 kg.

Review

Three trials collectively evaluated pharmacokinetics (PK), safety, and antiviral activity of all three components of ODEFSEY (emtricitabine 200mg, rilpivirine 25 mg, and tenofovir alafenamide 25mg) in pediatric patients weighing at least 25kg. Trial GS-US-292-0106 was a pediatric trial that evaluated cobicistat, emtricitabine, and tenofovir alafenamide and was reviewed under NDA 207561 for GENVOYA (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide). Trials TMC278-TiDP38-C213 and TMC278HTX2002 were pediatric trials that evaluated EDURANT (rilpivirine) and were under NDA 202022 (EDURANT) and NDA 219016 (EDURANT PED). Both GENVOYA and EDURANT are approved in pediatric patients covering the weight band proposed for Odefsey (at least 25 kg). Letters of authorization to cross-reference the NDAs for EDURANT, EDURANT PED, and GENVOYA were submitted to the ODEFSEY NDA.

Based on the Division's prior assessment of EDURANT and GENVOYA, the available PK, safety, and efficacy data support the use of ODEFSEY in pediatric patients weighing at least 25 kg.

Recommendation

We recommend approval of this supplement. The agreed upon changes to the ODEFSEY label are consistent with the current EDURANT, EDURANT PED, and GENVOYA labels. This supplement fulfills PMR 3403-1.

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/

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02/04/2025 02:13:03 PM

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