Addendum to the Combined Cross-Discipline Team Leader, Clinical, Clinical Pharmacology, and Division Director Review

Date	February 26, 2026
From	Sarita Boyd, PharmD Kimberly Struble, PharmD
Subject	Clinical Review Addendum
Application Type	NDA 220092
NDA/BLA # and Supplement#	NDA 205395-S29
Applicant	Janssen
Date of Submission	April 30, 2025 May 7, 2025 (supplement)
PDUFA Goal Date	February 28, 2026 March 7, 2026 (supplement)
Proprietary Name	Prezcobix PED Prezcobix
Established or Proper Name	Darunavir (DRV) and cobicistat (COBI)
Dosage Form(s)	Tablets for oral suspension (Prezcobix PED) Tablets (Prezcobix)
Applicant Proposed Indication(s)/Population(s)	PREZCOBIX and PREZCOBIX PED are indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) in treatment-naïve and treatment-experienced adults and pediatric patients 3 years of age and older weighing at least 15 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V).
Applicant Proposed Dosing Regimen(s)	Pediatric patients aged 3 years and older weighing at least 15 kg to less than 25 kg: One Prezcobix PED 600 mg darunavir/90 mg cobicistat tablet for oral suspension
Recommendation on Regulatory Action	Approve new tablet for oral suspension formulation and Approve (supplement) to align labeling
Recommended Indication(s)/Population(s)	Same as proposed
Recommended Dosing Regimen	Same as proposed
Cross-Reference	Letters of cross-reference were provided by Gilead Sciences for the following applications: • NDA 203094 (Tybost: cobicistat [COBI] tablets) • NDA 207561 (Genvoya: elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide, or E/C/F/TAF) • NDA 203100 (Stribild: elvitegravir/cobicistat/ emtricitabine/tenofovir disoproxil fumarate, or E/C/F/TDF)

ADDENDUM

PREA PMRs previously issued for NDA 205395

In addition to addressing PREA PMR 2845-1, these submissions address PREA PMR 2845-2, also issued at the time of NDA 205395 (Prezcobix) approval on January 29, 2015.

2845-2	Evaluate the pharmacokinetics, safety, and antiviral activity (efficacy) of darunavir and cobicistat fixed dose combination (FDC) age-appropriate formulation in HIV-infected pediatric subjects 6 years to less than 12 years of age and weighing at least 15 kg. The safety and antiviral activity (efficacy) of darunavir and cobicistat FDC age-appropriate formulation in pediatric subjects should be evaluated for a minimum of 24 weeks. A clinical trial in children ages 6 years to less than 12 years may not be required if the dosing recommendation for the FDC age-appropriate formulation can be supported by pediatric trials already conducted with the individual drug products and if the age-appropriate FDC produces similar exposures as the individual components.

A previous Prezcobix sNDA (S-28) partially addressed PREA PMR 2845-2. That sNDA resulted in approval of the lower strength, scored Prezcobix tablet (DRV/COBI 675 mg/150 mg) in pediatric patients weighing ≥25 kg to <40 kg. Because the weight band ≥15 kg to <25 kg was yet to be addressed, that sNDA did not fulfill PREA PMR 2845-2. Please refer to the integrated review for NDA 205395 S-28 (clinical reviewer: Dr. Antigone Kraft) for complete details.

The current NDA 220092 and sNDA 205395 (S-29) submissions address the remaining pediatric weight band of ≥15 kg to <25 kg, and the review team recommends approval of Prezcobix PED tablet for oral suspension (DRV/COBI 600 mg/90 mg) in this pediatric population. Please refer to the integrated review for these submissions for complete details. With the current submissions, PREA PMR 2845-2 is now considered fulfilled.

PREA triggered for NDA 220092

Prezcobix PED tablets for oral suspension is a new dosage formulation that triggers PREA. The indication will include use in pediatric patients ≥3 years of age and weighing ≥15 kg. A waiver for the pediatric study requirement is recommended for ages <3 years because DRV, a component of Prezcobix PED, is not recommended in pediatric patients <3 years of age due to toxicity and mortality observed in juvenile rats dosed with DRV. A waiver for the pediatric study requirement is also recommended for ages ≥3 years to <18 years weighing <15 kg because this product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age and weight group. In addition, multiple fixed-dose formulations would be required to be developed to accommodate the various weight bands in the small number of pediatric patients below 15 kg.

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