CLINICAL PHARMACOLOGY REVIEW

NDA/SDN	206353/305 (S-7) 205395/631 (S-16)
Submission Type	Efficacy supplement
Applicant Name	NDA 205395: Janssen NDA 206353: BMS
Submission Date	NDA 205395: 12/17/2019 NDA 206353: 12/6/2019
Generic Name	NDA 205395: Darunavir and cobicistat NDA 206353: Atazanavir and cobicistat
Brand Name	NDA 205395: Prezcobix NDA 206353: Evotaz
Dosage Form (Strength)	NDA 205395: Tablet (800 mg and 150 mg) NDA 206353: Tablet (300 mg and 150 mg)
Indication	Treatment of HIV-1 Infection
Review Team	Mario Sampson, PharmD, Vikram Arya, PhD, FCP

Based on Trial 128 in HIV-infected pediatric subjects aged ≥12 years, cobicistat (Tybost) labeling was updated 10/3/2019 to include approval of darunavir and cobicistat (DRV/c) for patients weighing ≥40 kg and approval of atazanavir and cobicistat (ATV/c) for patients weighing ≥35 kg (NDA 203094 Clinical Pharmacology reviews dated 8/2/2019 and addendum dated 10/1/2019). In this submission, section 12.3 (Pediatrics subsection) of Prezcobix and Evotaz labeling were updated to include this previously reviewed and approved information. In addition, language pertaining to withdrawn drug simeprevir was removed from section 7 of Prezcobix. We recommend approval of both efficacy supplements.

Reference ID: 4628108

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/s/

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06/19/2020 01:12:07 PM

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06/19/2020 01:22:22 PM