

CLINICAL PHARMACOLOGY REVIEW

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| 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: Prezco b ix 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 Prezco**b**ix 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 In addition, language pertaining to withdrawn drug simeprevir was removed from section 7 of Prezco**b**ix. We recommend approval of both efficacy supplements.

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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