CLINICAL AND CROSS DISCIPLINE TEAM LEADER REVIEW

Date	May 12, 2020
From	Sarita Boyd, PharmD (Clinical Reviewer) Adam Sherwat, MD (Medical Team Leader)
Subject	Clinical and Cross Discipline Team Leader Review
NDA/BLA # **Supplement#**	NDA 205395 S-16
Applicant	Janssen
Date of Submission	December 17, 2019
PDUFA Goal Date	October 17, 2020
Proprietary Name / Established (USAN) names	Prezcobix / darunavir and cobicistat (DRV/c)
Dosage forms / Strength	Film-coated tablet 800 mg/150 mg
Proposed Indication	Expansion of current indication to pediatric patients weighing at least 40 kg
Proposed Dosing Regimen	One tablet orally once daily with food
Recommended:	Approval of this supplement

Introduction

The Applicant submitted an efficacy supplement to seek approval of Prezcobic for pediatric patients weighing at least 40 kg.

Review

Trial GS-US-216-0128 evaluated PK, safety, and antiviral activity of the components of Prezcobix (darunavir 800 mg and cobicistat 150 mg) in combination with two nucleoside reverse transcriptase inhibitors in pediatric patients weighing at least 40 kg. This trial was reviewed under NDA 203094 for Tybost (cobicistat), which resulted in approval of Tybost with darunavir in pediatric patients covering the weight band proposed for Prezcobix (at least 40 kg). A letter of authorization to cross-reference the Tybost NDA was submitted to the Prezcobix NDA.

Based on the Division's prior assessment of Tybost with darunavir, the available PK, safety, and efficacy data support the use of Prezcobix in pediatric patients weighing at least 40 kg.

Recommendation

We recommend approval of this supplement. The agreed upon changes to the Prezcobix label are consistent with the current Tybost and Symtuza labels.

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/

SARITA D BOYD
06/16/2020 03:08:29 PM

ADAM I SHERWAT
06/16/2020 08:35:27 PM