

## CLINICAL AND CROSS DISCIPLINE TEAM LEADER REVIEW

<b>Date</b>	January 31, 2020
<b>From</b>	Sarita Boyd, PharmD (Clinical Reviewer) Adam Sherwat, MD (Medical Team Leader)
<b>Subject</b>	Clinical and Cross Discipline Team Leader Review
<b>NDA/BLA #</b>	NDA 210455
<b>Supplement#</b>	S-9
<b>Applicant</b>	Janssen
<b>Date of Submission</b>	July 11, 2019
<b>PDUFA Goal Date</b>	May 11, 2020
<b>Proprietary Name / Established (USAN) names</b>	Symtuza / darunavir, cobicistat, emtricitabine, and tenofovir alafenamide (D/C/F/TAF)
<b>Dosage forms / Strength</b>	Film-coated tablet / 800 mg, 150 mg, 200 mg, and 10 mg
<b>Proposed Indication</b>	Expansion of current indication to pediatric patients weighing at least 40 kg
<b>Proposed Dosing Regimen</b>	One tablet orally once daily with food
<b>Recommended:</b>	Approval of this supplement

### Introduction

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

### Review

Two trials collectively evaluated PK, safety, and antiviral activity of all four components of Symtuza (darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg, and tenofovir alafenamide 10 mg) in pediatric patients weighing at least 40 kg. 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). Trial GS-US-216-0128 was a pediatric trial that evaluated darunavir and cobicistat and was reviewed under NDA 203094 for Tybost (cobicistat). Both Genvoya and Tybost with darunavir are approved in pediatric patients covering the weight band proposed for Symtuza (at least 40 kg). Letters of authorization to cross-reference the NDAs for Tybost and Genvoya were submitted to the Symtuza NDA.

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

### Recommendation

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

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