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 206353 S-7
Applicant	Bristol-Myers Squibb
Date of Submission	December 6, 2019
PDUFA Goal Date	October 6, 2020
Proprietary Name / Established (USAN) names	Evotaz / atazanavir and cobicistat (ATV/c)
Dosage forms / Strength	Film-coated tablet 300 mg/150 mg
Proposed Indication	Expansion of current indication to pediatric patients weighing at least 35 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 Evotaz for pediatric patients weighing at least 35 kg.

Review

Trial GS-US-216-0128 evaluated PK, safety, and antiviral activity of the components of Evotaz (atazanavir 300 mg and cobicistat 150 mg) in combination with two nucleoside reverse transcriptase inhibitors in pediatric patients weighing at least 35 kg. This trial was reviewed under NDA 203094 for Tybost (cobicistat), which resulted in approval of Tybost with atazanavir in pediatric patients covering the weight band proposed for Evotaz (at least 40 kg). A letter of authorization to cross-reference the Tybost NDA was submitted to the Evotaz NDA.

Based on the Division's prior assessment of Tybost with atazanavir, the available PK, safety, and efficacy data support the use of Evotaz in pediatric patients weighing at least 35 kg.

Recommendation

We recommend approval of this supplement. The agreed upon changes to the Evotaz label are consistent with the current Tybost label.

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/s/

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