INTRODUCTION

- Body size is an important variable of drug exposure
- Pharmacokinetic (PK) models suggest size-based adjustments to achieve target drug exposure
- Rezafungin is a novel echinocandin with a distinctive PK profile (long half-life, extensive tissue distribution, and front-loaded drug exposure) that allow for once-weekly dosing and efficacy2,3
- Rezafungin is currently in Phase 3 development for treatment of candidiasis and invasive candidiasis (IC) [ReSTORE; NCT03667690] and for prevention of invasive fungal disease caused by Candida, Aspergillus, and Pneumocystis in blood and marrow transplant recipients [ReSPECT; NCT04368559]

OBJECTIVES

To evaluate outcomes based on patient body mass index (BMI) in a subanalysis of the Phase 2 STRIVE trial of rezafungin in the treatment of candidemia and/or IC [NCT02734862] compared with caspofungin (Fig. 1)4,5

Figure 1. Treatment Groups of the Phase 2 STRIVE Trial

METHODS

Data were stratified by BMI categories (<30 kg/m² and ≥30 kg/m²) and assessed for

- Safety: treatment-emergent adverse events (TEAEs)
- Efficacy: overall response [resolution of clinical signs of infection and mycological eradication], mycological response, and investigator assessment of clinical response
- PK: area under the curve [AUC] from RZF-treated patients in the first part of the trial with PK data available for analysis

RESULTS

Mean BMI Values

- Rezafungin Group 1, 26.9 kg/m²; rezafungin Group 2 and caspofungin arms, 26.8 kg/m²

Safety

- TEAEs rates showed no concerning trends (Table 1)

Efficacy

- Outcomes by BMI categories were similar (Table 2)

PK

- AUC ranges by BMI overlapped (Fig. 2). Mean ± SD AUC was ~20% lower for the higher BMI category (615 ± 104 vs 741 ± 194 μg·h/mL, respectively)

CONCLUSIONS

- Rezafungin safety, efficacy, and PK in STRIVE was consistent across BMI categories
- These results suggest that rezafungin dose adjustments in obese patients are not necessary
- These findings contribute to the evaluation of rezafungin in a range of patient populations and its further development

REFERENCES


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