**INTRODUCTION**

Rezafungin (RZF) is a novel, next-generation echinocandin with distinctive pharmacokinetics/pharmacodynamics, including prolonged half-life and front-loaded plasma exposure, and improved safety and stability over existing systemic antifungals, which allow for once-weekly IV administration and optimized pharmacometrics of efficacy. STRIVE is a global, double-blind, randomized trial (NCT02734862) that evaluated the safety and efficacy of once-weekly RZF in the treatment of candidemia and/or invasive candidiasis (IC). After successful completion of Part A, a second randomization (Part B) was conducted. Rezafungin is currently in Phase 3 (Ph3) development.

**METHODS**

Adults (≥18 y) with systemic signs and mycological confirmation of candidemia and/or IC were randomized to RZF once-weekly or standard of care (SOC) with caspofungin (CAS) for ≥14 days (≤4 weeks) (Figure 1). The study objective was to evaluate the safety and tolerability of RZF and overall success at Day 14 (Box 1).

**RESULTS**

Of 207 patients enrolled, 183 patients were included in the mITT population. Treatment groups were well balanced and matched in demographics and baseline characteristics (data not shown), including APACHE II scores (mean ± SD: 13.8 ± 7.1, N=207). Patients with IC comprised ~21% of the combined population.

**Safety**

- No concerning safety trends were observed
- Incidence of ≥1 TEAE was 120/134 (89.6%) among the RZF-treated (pooled) and 55/68 (80.9%) in the SOC group
- Rates of TEAEs leading to study discontinuation were comparable between RZF-treated (pooled) (5.2%) and SOC patients (5.9%)
- SAEs were observed in 47.0% and 42.6% of the RZF-treated and SOC groups, respectively

**Efficacy**

- RZF 400 mg/200 mg demonstrated greater efficacy than SOC on the primary and key endpoints (Table 1)
- Across all groups, RZF 400 mg/200 mg had the highest rates of overall success and clinical cure and the lowest rate of 30-day ACM mortality in the Safety Population

**CONCLUSIONS**

- RZF was safe and efficacious in the Phase 2 STRIVE trial of RZF treatment in patients with candidaemia and/or IC
- No concerning safety trends were observed, and RZF was generally comparable with SOC
- RZF 400 mg/200 mg once weekly, the dosing regimen in the ongoing Ph3 trial (ReSTORE; NCT03667690), demonstrated greater efficacy than SOC and the most favorable efficacy of all treatment arms
- The results from STRIVE Part B, combined with the previous success of Part A, demonstrate the safety and efficacy of RZF and supports its Ph3 development for the treatment of candidaemia and/or IC

**REFERENCES**

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