INTRODUCTION

• The overall safety and tolerability of echinocandins has been established since their introduction over 20 years ago. However, hepatic toxicity has been reported with caspofungin and the other approved echinocandins.

• Patients requiring antifungal treatment are often critically ill or have comorbidities that may affect hepatic function.

• Rezafungin (RZF) is a novel next-generation echinocandin in Phase 3 development for treatment of candidemia and invasive candidiasis (IC) [ReSTORE; NCT03667690] and candidemia and/or IC (Table 1).

• Non-clinical data did not show adverse hepatic effects, and Phase 1 trials did not demonstrate liver function abnormalities.

• STRIVE (Phase 2; NCT02734862) compared the safety and efficacy of RZF with caspofungin (CAS) in patients with candidemia and/or IC (Table 3).

• The ongoing Phase 3 treatment trial (ReSTORE; NCT03667690) will provide further data on rezafungin safety and contribute to the evidence of safety in the echinocandin class of antifungals.

METHODS

• Adults (aged ≥18 y) were randomized to receive RZF or CAS.

• Safety was evaluated by treatment-emergent adverse event (TEAE) data and laboratory chemistry values.

RESULTS

• High rates of TEAEs were observed in all treatment groups, reflecting the high underlying medical acuity of the trial population (Table 2).

• Rates of TEAEs leading to study drug discontinuation were 5.2% for RZF (RZF groups pooled) and 5.9% in the CAS group (Table 2).

• Overall, no concerning trends between groups or between treatments (RZF groups pooled versus caspofungin) were observed in the occurrence of TEAEs or laboratory values evaluated with a post-baseline increase of ≥2 toxicity grades (Table 3).

• There were no other substantial post-baseline changes or unexpected findings in lab chemistry values or hematology test results.

REFERENCES


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