Candidaemia and IC are life-threatening fungal infections, particularly for vulnerable patient populations such as the critically ill, elderly, post-transplantation, and other hospitalized patients with serious medical conditions.\(^4\) Rezafungin is a once-weekly, next-generation echinocandin in development for treatment of candidemia and IC and for prevention of invasive fungal disease caused by Candida, Aspergillus, and Pneumocystis spp. in patients undergoing allogeneic hematopoietic cell transplantation and with underlying neutropenia.

A Phase 2 trial (STRIDE; NCT03743849) demonstrated the safety and efficacy of rezafungin in patients with candidemia and/or IC.\(^5\) Herein are results of the recently completed ReSTORE trial (NCT03667990), the pivotal Phase 3 non-inferiority (NI) trial of rezafungin once daily for the treatment of candidemia and IC.

**METHODS**

Rezafungin is a once-weekly, next-generation echinocandin in development for treatment of candidemia and IC and for prevention of invasive fungal disease caused by Candida, Aspergillus, and Pneumocystis spp. in patients undergoing allogeneic hematopoietic cell transplantation and with underlying neutropenia.

A Phase 2 trial (STRIDE; NCT03743849) demonstrated the safety and efficacy of rezafungin in patients with candidemia and/or IC.\(^5\) Herein are results of the recently completed ReSTORE trial (NCT03667990), the pivotal Phase 3 non-inferiority (NI) trial of rezafungin once daily for the treatment of candidemia and IC.

**RESULTS**

**Safety**

- No concerning safety trends were observed in overall rates of adverse events (AEs) (Table 4) or serious AEs (SAEs) (Table 5).
- Of treatment-emergent AEs (TEAEs) occurring in >5% of subjects, the most common in each treatment arm were:
  - Rezafungin group: Pyrexia (n=14, 13.3%), hypokalemia (n=13, 13.3%), pneumonia (n=10, 10.2%), septic shock (n=10, 10.2%), and anaemia (n=9, 9.2%).
  - Caspofungin group: Hypokalaemia (n=9, 9.2%), septic shock (n=9, 9.2%), anaemia (n=9, 9.2%), acute kidney injury (n=8, 8.2%), and diarrhoea (n=7, 7.1%).

**CONCLUSIONS**

- Rezafungin was found to be non-inferior to caspofungin for both of its primary endpoints (all-cause mortality at Day 30, US FDA; global cure at Day 14, EMRA).
- Rates of AEs and SAEs were similar between study arms.
- Exploratory endpoints of early efficacy (mycological eradication and global cure at Day 5, TTNBC) support the conclusion that rezafungin is efficacious for the treatment of candidemia and IC.
- Further analyses of this pivotal, phase 3, NI trial are underway.

**REFERENCES**