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Analysis of outcomes by geographic region of enrolment in STRIVE, the phase II of rezafungin for the treatment of *candida*emia and invasive candidiasis

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Background: Rezafungin is a novel echinocandin in Phase 3 development. STRIVE (NCT02734862) is the global, Phase 2 trial of rezafungin once-weekly for treatment of candidemia and/or IC versus standard of care. Results of STRIVE were evaluated by geographic region to assess for differences in the complete trial population.

Materials/methods: Data were stratified by region of enrollment (EU vs North America [NA]) and analysed for differences in patient demographics and baseline characteristics, treatment patterns, and efficacy outcomes.

Results: Patients enrolled in EU (N=131) were older than in NA (N=76) (mean, 64 vs 52 years, respectively) and were predominantly male (61.1%) and White (93.1%). The NA population was 50% male and comprised 23.7% Black or African-American patients. On average, NA patients weighed more and had higher BMI (+2.3 kg/m^2).

The same leading *Candida* species were isolated at baseline in both regions but with differing distribution. *Candida albicans* comprised 44% of EU isolates, and proportions of *Candida parapsilosis*, *Candida glabrata*, and *Candida tropicalis* were similar (13-18%). In NA, *C. albicans* accounted for 52% of isolates, followed by 25% *C. glabrata* and 7% each for *C. parapsilosis* and *C. tropicalis*.

In both regions, 55% of patients received 8-14 days of IV treatment; 27% of EU patients received >14 days versus 18% in NA. Fewer patients in EU were switched to oral step-down (24.4% vs 42.7% NA). The NA population had a higher proportion of patients with IC (26.3% vs 17.6% EU).

Outcomes were comparable between regions except for higher rates of overall success in EU patients treated with rezafungin 400 mg in Week 1 followed by 200 mg once weekly, compared with the NA cohort (Table).

Conclusions: The Phase 2 STRIVE trial demonstrated few differences by region in demographic and baseline characteristics. The EU population was slightly older, and NA patients were generally heavier. Non-*albicans* species were predominant in the EU and comprised almost half of the NA isolates. Efficacy by region showed no consistent trends, although interpretation of efficacy-related differences are limited by group size. Results of this analysis may inform future evaluation of data from the rezafungin clinical trial program.

Table. Overall Response by Geographic Region

Geographic Region of Enrollment	Overall Response - Success at Day 14, % (n/N)		
	Rezafungin 400mg Wk1/ 400mg QWk	Rezafungin 400mg Wk 1/ 200mg QWk	Caspofungin 70 mg/50 mg QD
Europe	60.4 (32/53)	82.8 (24/29)	69.2 (27/39)
North America	60.9 (14/23)	64.7 (11/17)	63.6 (14/22)

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