Analysis of outcomes by geographic region of enrolment in STRIVE, the phase II of rezafungin for the treatment of candidemia 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/m²).

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

<table>
<thead>
<tr>
<th>Geographic Region of Enrollment</th>
<th>Overall Response - Success at Day 14, % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rezafungin 400mg Wk1/ 400mg QWk</td>
</tr>
<tr>
<td>Europe</td>
<td>60.4 (32/53)</td>
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<tr>
<td>North America</td>
<td>60.9 (14/23)</td>
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</tbody>
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