Analysis of Outcomes by Geographic Region of Enrollment in STRIVE, the Phase 2 Trial of Rezafungin for the Treatment of Candidemia and Invasive Candidiasis (IC)

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INTRODUCTION
Rezafungin is a novel echinocandin in Phase 3 development for treatment of candidemia and invasive candidiasis (IC)1 and for prophylaxis against invasive fungal disease caused by Candida, Aspergillus, and Pneumocystis in bone and marrow transplantation.2 STRIVE (NCT02734862) is the global, Phase 2 trial of once-weekly IV rezafungin for treatment of candidemia and/or IC versus standard-of-care (IV caspofungin+optional oral fluconazole).3

OBJECTIVES
Data from the complete STRIVE trial were evaluated for differences by geographic region.

METHODS
Patients were randomized to 1 of 3 groups (Fig 1).3 Data were stratified by region of enrollment (Europe [EU] or North America [NA]) and analysed by patient demographics, baseline characteristics, treatment patterns, and efficacy outcomes.4

RESULTS
Patient Population (ITT Population – all randomized)
• Patients in the EU were on average older, weighed less, and had lower BMI (Table 1).
• EU population was 93.1% white; the NA population comprised 23.7% Black or African-American patients.
• Rate of IC was 26.35 in NA vs 17.6% in EU

Table 1. Demographics and baseline characteristics (ITT) (EU population vs NA population)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Rezafungin 400/400 mg QWk</th>
<th>Rezafungin 200/200 mg QWk</th>
<th>Caspofungin 70/50 mg QD</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n/N (%)</td>
<td>EU 32/54 (95.3)</td>
<td>21/34 (61.8)</td>
<td>27/43 (62.8)</td>
<td>80/151 (81.1)</td>
</tr>
<tr>
<td>Age, y (mean range)</td>
<td>NA 12/27 (44.4)</td>
<td>15/23 (65.2)</td>
<td>11/26 (42.3)</td>
<td>38/76 (50.0)</td>
</tr>
<tr>
<td>No. patients ≥ 65 y</td>
<td>EU 64 (26.8)</td>
<td>66 (30.9)</td>
<td>63 (24.9)</td>
<td>64 (24.9)</td>
</tr>
<tr>
<td>No. patients ≥ 80 y</td>
<td>NA 51 (21.7)</td>
<td>51 (24.9)</td>
<td>54 (23.8)</td>
<td>52 (20.4)</td>
</tr>
<tr>
<td>Weight, kg (mean ± SD)</td>
<td>EU 28 (11.9)</td>
<td>20 (11.8)</td>
<td>22 (11.2)</td>
<td>70 (32.4)</td>
</tr>
<tr>
<td>BMI, kg/m² (mean ± SD)</td>
<td>NA 4 (1.8)</td>
<td>5 (2.7)</td>
<td>7 (2.9)</td>
<td>16 (21.1)</td>
</tr>
</tbody>
</table>

Table 2. Overall response by treatment group and region (mITT)

<table>
<thead>
<tr>
<th>Overall Response at Day 14 (mITT Population)</th>
<th>Rezafungin 400/400 mg QWk</th>
<th>Rezafungin 200/200 mg QWk</th>
<th>Caspofungin 70/50 mg QD</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU - Success</td>
<td>32/53 (60.4)</td>
<td>24/26 (82.8)</td>
<td>27/39 (69.2)</td>
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<tr>
<td>Excl. Indeterminate*</td>
<td>32/53 (62.7)</td>
<td>24/28 (85.7)</td>
<td>27/39 (69.2)</td>
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<tr>
<td>NA - Success</td>
<td>14/23 (60.9)</td>
<td>11/17 (64.7)</td>
<td>14/22 (63.6)</td>
<td></td>
</tr>
<tr>
<td>Excl. Indeterminate*</td>
<td>14/15 (93.3)</td>
<td>11/15 (73.3)</td>
<td>14/19 (73.7)</td>
<td></td>
</tr>
</tbody>
</table>

*Excludes patients for whom outcome could not be assessed due to missing data point(s).

Treatment Patterns (Safety Population)
• 55% of patients received 8–14 days of IV treatment
• The duration of IV treatment exceeded 14 days in 27% of EU patients and 18% of NA patients.
• A smaller proportion of EU patients were switched to oral step-down vs NA (24.4% vs 47.2%, respectively).

Efficacy – Overall Response at Day 14 (mITT Population)
• Rates were comparable between regions, except for patients in the rezafungin 400 mg/200 mg group (Table 2).

Figure 2. Distribution of Candida spp. at Enrollment (mITT)

Distribution of Candida at Enrollment (mITT Population)
• The leading Candida species at baseline showed differing distributions by region (Figure 2)

Figure 3. Treatment Patterns

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REFERENCES
1. The ReSTORE Trial (NCT03667690).
2. The ReSPECT Trial (NCT04368559).

CONCLUSIONS
• The Phase 2 STRIVE trial demonstrated few differences by region in demographic and baseline characteristics.
• Non-albicans Candida species were predominant in the EU.
• Efficacy outcomes showed no consistent trends; interpretation of efficacy-related differences are limited by group size.
• This analysis by geographic region may inform future evaluation of data from the rezafungin clinical trial program.

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