Clinical Efficacy and Safety of Rezafungin (CD101): Results from STRIVE, a Randomized, Double-blind, Multicenter, Phase 2 Study in the Treatment of Candidia and/or Invasive Candidiasis

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RESULTS (cont’d)

Safety
No concerning trends in AEs were observed with rezafungin treatment (Table 2).

Table 2: Summary of Adverse Events (Safety)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group 1: RFP (n=28)</th>
<th>Group 2: RFP + rezafungin (n=28)</th>
<th>Group 3: CAS (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEAE (%)</td>
<td>36 (12.9)</td>
<td>32 (91.4)</td>
<td>20 (71.4)</td>
</tr>
<tr>
<td>Serious AE</td>
<td>13 (37.1)</td>
<td>7 (21.9)</td>
<td>3 (10.7)</td>
</tr>
<tr>
<td>Mortality</td>
<td>7 (21.9)</td>
<td>7 (21.9)</td>
<td>3 (10.7)</td>
</tr>
</tbody>
</table>

RESULTS (cont’d)

Efficacy
Rezafungin demonstrated efficacy in patients with candidia and/or IC (Table 3), with the highest rates of Overall Success and Clinical Cure observed in Group 2 (rezafungin 400mg/200mg twice daily regimen).

Table 3: Overall Response and PI Assessment of Clinical Response at Day 14 and All Day Mortality at Day 30 (ITT)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group 1: RFP (n=28)</th>
<th>Group 2: RFP + rezafungin (n=28)</th>
<th>Group 3: CAS (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>19 (67.8)</td>
<td>25 (75.8)</td>
<td>13 (46.4)</td>
</tr>
<tr>
<td>Indeterminates</td>
<td>7 (21.9)</td>
<td>7 (21.9)</td>
<td>3 (10.7)</td>
</tr>
<tr>
<td>Mortality (30)</td>
<td>5 (17.9)</td>
<td>1 (3.0)</td>
<td>1 (3.0)</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• Rezafungin IV demonstrated clinical safety and efficacy in the treatment of candidemia/C.
• Rezafungin was safe and well tolerated at both dose regimens.
• High numbers of Indeterminate responses in Group 1 accounted for an apparent difference in the rates of Overall Success and Clinical Cure.
• The rezafungin 400mg/200mg once-weekly dosing regimen had the highest efficacy in all assessments.
• These results support the use of rezafungin for further clinical phase in 3 Phase.

REFERENCES


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