Outcomes by Body Mass Index (BMI) in the STRIVE Phase 2 Trial of Once-Weekly Rezafungin for Treatment of Candidemia and Invasive Candidiasis Compared with Caspofungin

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INTRODUCTION

• A 'silent epidemic' of antifungal underdosing in the treatment of invasive disease in the critically ill may also affect special populations, such as the obese[1]
• Body size is an important variable affecting drug exposure
• Pharmacokinetic (PK) models of antifungal dosing suggest size-based adjustments to achieve target drug exposure

Rezafungin is a novel echinocandin distinguished by a PK profile that includes long half-life, extensive tissue distribution, and front-loaded drug exposure, lending to its potential efficacy and safety, efficacy, and PK in STRIVE was consistent across BMI categories

Rezafungin is currently in Phase 3 development for treatment of candidemia and invasive candidiasis (IC) (ReSTORE; NCT03667690) and for prevention of invasive fungal disease caused by Candida, Aspergillus, and Pneumocystis in blood and marrow transplant recipients (ReSPECT; NCT04368559).

A sub-analysis of results from the Phase 2 STRIVE trial of rezafungin QWk in the treatment of candidemia and/or IC (NCT02734682) compared with caspofungin once daily (Figure 1) was conducted to evaluate outcomes based on patient BMI

RESULTS (cont’d)

Efficacy outcomes at Day 14 were similar between BMI categories (Table 2)

RESULTS

Mean BMI values: rezafungin Group 1, 26.9 kg/m²; rezafungin Group 2 and caspofungin arms, 26.8 kg/m²

Safety

• TEAE rates were generally similar between categories (Table 1), with no concerning safety trends

Table 1. Summary of TEAEs by BMI Category (<30 kg/m² vs ≥30 kg/m²) from the STRIVE Trial (Safety Population)

<table>
<thead>
<tr>
<th>TEAE</th>
<th>BMI &lt;30 kg/m²</th>
<th>BMI ≥30 kg/m²</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Response</td>
<td>34 (58.6)</td>
<td>26 (52.6)</td>
<td></td>
</tr>
<tr>
<td>Mycological Response</td>
<td>37 (69.4)</td>
<td>26 (51.9)</td>
<td></td>
</tr>
<tr>
<td>Investigator assessment of Clinical Cure</td>
<td>40 (70.2)</td>
<td>28 (53.8)</td>
<td></td>
</tr>
<tr>
<td>Investigator assessment of Clinical Cure</td>
<td>33 (58.1)</td>
<td>28 (53.8)</td>
<td>16 (29.6)</td>
</tr>
</tbody>
</table>

Table 2. Efficacy Outcomes by BMI Category (<30 kg/m² vs ≥30 kg/m²) in STRIVE (mITT Population)

<table>
<thead>
<tr>
<th>Outcome at Day 14</th>
<th>BMI &lt;30 kg/m²</th>
<th>BMI ≥30 kg/m²</th>
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RESULTS (cont’d)

Conclusions

Rezafungin safety, efficacy, and PK in STRIVE was consistent across BMI categories

• These results suggest that rezafungin dose adjustments in obese patients are not necessary
• These findings contribute to the evaluation of rezafungin in a range of patient populations and its further development

REFERENCES


ACKNOWLEDGMENTS

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