**RESULTS**

**Microbiological efficacy outcomes in patients with history of infectious hepatitis**

Delafloxacin (DLX) was effective and well-tolerated compared to vancomycin/aztreonam (VAN/AZ) in treating patients with acute bacterial skin and skin structure infections (ABSSSI) and history of infectious hepatitis.

**Table 1. All related treatment-emergent adverse events occurring in ≥ 1% of patients. SAFETY ANALYSIS SET, PATIENTS WITH HISTORY OF INFECTIOUS HEPATITIS, POOLED PHASE 3.**

<table>
<thead>
<tr>
<th>Event</th>
<th>DLX</th>
<th>VAN/AZ</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>176/220 (80.0)</td>
<td>161/161 (75.0)</td>
<td>5.0% (−1.8, 12.8)</td>
</tr>
</tbody>
</table>

**Table 2. Summary of patient demographics and baseline characteristics of ABSSSI patients with history of infectious hepatitis, pooled phase 3.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>DLX (N=217)</th>
<th>VAN/AZ (N=217)</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>120 (55.0)</td>
<td>123 (57.2)</td>
<td>−2.2% (−8.8, 4.4)</td>
</tr>
<tr>
<td>≥ 75 cm</td>
<td>57 (26.1)</td>
<td>58 (26.8)</td>
<td>0.7% (−5.4, 6.7)</td>
</tr>
<tr>
<td>≥ 25 kg (actual weight)</td>
<td>10/10 (100)</td>
<td>10/10 (100)</td>
<td>0.0% (−1.3, 1.3)</td>
</tr>
</tbody>
</table>

**Table 3. Baseline eligible pathogens.**

**Table 6: Overall summary of adverse events.**

**References**


**DISCUSSION/CONCLUSIONS**

- Patients with history of infectious hepatitis can have complicating medical history such as active substance abuse. In this study, almost all of the patients with history of infectious hepatitis had a current or history of substance abuse.
- There were no reports of cases meeting the Hy's law definition in DLX-treated patients.
- The incidence of serious adverse events (SAEs) was comparable in the two treatment arms. DLX was noninferior to VAN/AZ for ABSSSI if lower than 20% decrease in lesion size.
- DLX was as effective as VAN/AZ against key ABSSSI pathogens like P. aeruginosa and S. aureus.

**CONCLUSION**

- Delafloxacin (DLX) is an investigational emergent fluoroquinolone antibiotic, which is in development for the treatment of acute bacterial skin and skin structure infections (ABSSSI).
- In a population of patients with history of infectious hepatitis, treating with DLX was as effective as treating with VAN/AZ.
- DLX is as effective and well-tolerated as VAN/AZ in treating patients with ABSSSI and history of infectious hepatitis.
- DLX was not associated with the risk of resistance development relative to VAN/AZ.