Introduction: Iclaprim, a diaminopyrimidine-based, was compared with data from the pooled ASSIST studies. -2 and -2 studies evaluated iclaprim 80 mg fixed dose vs vancomycin 15 mg/kg; study drugs were infused over 2 hours Q12h for 5-14 days.

Conclusions: The population model indicated that patients in the REVIVE studies had a median AUC of 5924 mg*h/mL and a median Cmax of 651 mg/L (median Cmax of 687 mg/mL). The Cmax was reduced by 7.3% with the iclaprim 80 mg fixed dose versus 2 hours compared to the weight 15 mg/kg dose. These differences are similar to those due to changes in the dosing and infusion times. The main reason for the change in the main PK parameters for the REVIVE and ASSIST studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients who Received</th>
<th>Fixed 2h Dose</th>
<th>Weight-based doses</th>
<th>Cmax (mean)</th>
<th>T&gt;MIC</th>
<th>AUC/MIC</th>
<th>T&gt;MIC (efficacy)</th>
<th>Lower Cmax (safety)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSIST &amp; REVIVE</td>
<td>1,280 (28)</td>
<td>80 mg fixed dose</td>
<td>80 mg fixed dose</td>
<td>65.3 (6.46)</td>
<td>90 (27.5)</td>
<td>65.3 (6.46)</td>
<td>90 (27.5)</td>
<td>65.3 (6.46)</td>
</tr>
</tbody>
</table>

References:

We acknowledge the efforts of the patients, site staff and investigators in the REVIVE-1 and REVIVE-2 studies.

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