Iclaprim Use Across Various Subpopulations Treated for Bacterial Skin and Skin Structure Infections

Stephanie Noviello1, Thomas Lodise2, William O’Riordan3, Pascal Winnen4, David B. Huang5, Lynda Berne6

1MotifBioSciences, Princeton, New Jersey, USA; 2Albany College of Pharmacy and Health Sciences, Albany, New York, USA; 3eStudySite, San Diego, California, USA; 4Hemex, Liestal, Switzerland; 5Rutgers New Jersey Medical School, Trenton, New Jersey, USA; 6RAL Pharma Consulting, Princeton, New Jersey, USA

Clinical Development

Methods

• REVIVE studies for ABSSSI (Figure 1)
  - Randomized (1:1), double-blind, multicenter studies of fixed-dose iclaprim 80 mg Q12h compared with vancomycin 15 mg/kg Q12h, both infused over 2h, for 5-14 days.
  - Primary endpoint: Early clinical response (ECR) defined as ≥20% reduction in lesion size at 48-72 hours after initiating study drug compared with baseline in the ITT population.
  - 10% margin of noninferiority

• ASSIST studies for complicated skin and skin structure infections (cSSSI) (Figure 2)
  - Randomized (1:1), double-blind, multicenter studies of weight-based iclaprim 0.8 mg/kg Q12h compared with linezolid 600 mg Q12h, both infused over 30 minutes, for 10-14 days.
  - Primary endpoint: Test of cure response (TOC) defined as clinical cure 7-10 days after end of treatment in the ITT population.
  - 12.5% margin of noninferiority

Results

• Overall, 1093 patients with cSSSI/ABSSSI have been exposed to iclaprim in the Phase 3 studies with median treatment durations of 7 and 10 days in REVIVE and ASSIST studies, respectively.
• Demographics and baseline characteristics are shown in Table 1.
• 12-15% of the populations were ≥65 years old.
• Comorbidities included diabetes in 9-12% and renal impairment in 15-41% of patients.

Table 1. Demographics and baseline characteristics of iclaprim-treated patients in the Phase 3 REVIVE and ASSIST studies.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>REVIVE Population</th>
<th>ASSIST Population</th>
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<tbody>
<tr>
<td>Gender, n (%), Female/Male</td>
<td>495/605 (81%)</td>
<td>500/500 (100%)</td>
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<td>Age, years, mean (SD)</td>
<td>57.7 (16.5)</td>
<td>58.2 (15.1)</td>
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<td>BMI, kg/m2, mean (SD)</td>
<td>26.9 (5.0)</td>
<td>26.7 (4.8)</td>
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<td>Diabetes, n (%)</td>
<td>50 (8.1)</td>
<td>172 (34.4)</td>
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<tr>
<td>Obesity, n (%)</td>
<td>326 (55.0)</td>
<td>419 (83.8)</td>
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<tr>
<td>Renal impairment, n (%)</td>
<td>195 (39.4)</td>
<td>206 (41.2)</td>
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<td>Males, n (%), ≥65 years/Obese/Obese</td>
<td>100/141 (23%)</td>
<td>124/206 (60%)</td>
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Abbreviations: AE=adverse event, BMI=body mass index, DC=discontinuation, SAEs, serious AEs.

Conclusions

• A broad range of patients (N=1093) with Gram positive cSSSI/ABSSSI, including elderly and/or with co-morbid conditions such as diabetes, obesity, and renal impairment have been treated with favorable efficacy and safety with iclaprim in the clinical development program.
• Fewer discontinuations of iclaprim due to adverse events occurred among the elderly and diabetic patients.

References


Contact

David B. Huang, MD, PhD
MotifBio
Liestal, Switzerland
5 Independence Way, Suite 300
Princeton, NJ 08540
David.huang@motifbio.com