A Randomized, Double-Blind, Multi-Center Study to Evaluate the Efficacy and Safety of Oral Solithromycin (CEM-101) Compared to Oral Levofloxacin in the Treatment of Patients with Community Acquired Bacterial Pneumonia

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ABSTRACT

INTRODUCTION

STUDY OBJECTIVES & TREATMENT

• To assess the clinical success rate at the Test-of-Cure visit (5-10 days post completion of therapy) of oral solithromycin versus oral levofloxacin in the treatment of CABP, in the intent-to-treat (ITT) and clinically-evaluable (CE) populations.

• To assess the safety and tolerability of oral solithromycin compared to oral levofloxacin

• To assess the per-patient microbiological success rates of oral solithromycin compared to oral levofloxacin

RESULTS

Table 1: Key Safety Outcomes

<table>
<thead>
<tr>
<th>Treatment Arm</th>
<th>Serious AEs</th>
<th>AE Discontinuations</th>
<th>GI AEs</th>
<th>Diarrhea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solithromycin</td>
<td>2 (2.9%)</td>
<td>1 (1.5%)</td>
<td>10 (14%)</td>
<td>4 (5.9%)</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>3 (4.4%)</td>
<td>1 (1.6%)</td>
<td>7 (10.3%)</td>
<td>4 (5.9%)</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• Solithromycin performed very well in this Phase 2 trial

• Safety
  - Fewer drug discontinuations due to AEs (0% vs 6%) in
  - Fewer study subjects with SAEs (2 vs 7 subjects)
  - Fewer treatment emergent AEs (30% vs 46%)
  - Fewer GI related AEs (14% vs 26%)
  - No liver safety or QT/QTc concerns
  - No bitter aftertaste