Subjects with at least 1 episode of infection of the complete ITT population and ME population at TOC were included in the following analyses at the EOT, and FU end points. IIT, MIT, ETT; cIAI-CDI or TOA or M66-GIT or (TOR).

Microbiological response categories were eradication, presumptive eradication, persistence, persistence with decreased susceptibility, presumed persistence, or indeterminate (assessment not possible).

- Microbiological response categories were eradiation (reduction in CFU to <10^3 CFU/mL), presumptive eradication, persistence, persistence with decreased susceptibility, presumed persistence, or assessment not possible.

Safety: evaluations in all patients in the ITT population were conducted for safety.

Results:

**Table 1:** Demographics – Overall and by Baseline Renal Function in the micro-ITT population

<table>
<thead>
<tr>
<th>Group (N)</th>
<th>CrCl [min, max]</th>
<th>ETV % Cure</th>
<th>ETV % EOT</th>
<th>CR % Cure</th>
<th>CR % EOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>All (N=466)</td>
<td>107 [5, 206]</td>
<td>86.8</td>
<td>87.4</td>
<td>0.8</td>
<td>71.5</td>
</tr>
<tr>
<td>All (N=446)</td>
<td>107 [8, 266]</td>
<td>87.0</td>
<td>92.1</td>
<td>3.3</td>
<td>74.2</td>
</tr>
<tr>
<td>All (N=137)</td>
<td>153 [130, 240]</td>
<td>87.9</td>
<td>89.7</td>
<td>0.1</td>
<td>118.1</td>
</tr>
</tbody>
</table>

**Table 2:** IGNITE1 – Efficacy and Overall by Baseline Renal Function in the micro-ITT population

**Table 3:** IGNITE1 Safety data in the ITT population

**Conclusions:**

- This study met its primary efficacy endpoint, demonstrating non-inferiority of ETV to ETP in the treatment of cIAI.
- There were no differences in clinical efficacy in any renal function strata evaluated.
- Erovacycline may offer alternative therapy in adult patients with cIAI, including abnormal renal function.

**Abstract**

**Effects of Renal Function on Efficacy in IGNITE1: A Phase 3 Study to Evaluate the Efficacy and Safety of Erovacycline (ERV) in Patients with Community-Acquired Infections with a Renal Impairment**

- This study met its primary efficacy endpoint, demonstrating non-inferiority of Erovacycline to ETP in the micro-ITT population.
- This study was designed to demonstrate non-inferiority (NI) of ETV 1.0 mg/kg IV q12h to ETP 1.0 g q48h. The primary efficacy endpoint was to compare the clinical response (CR) to ETV and ETP in ITT and micro-ITT population (MI-ITT) and efficacy (EVT) to ETP.

**Figure 1:** IGNITE1 Trial Design – Overall and by Baseline Renal Function

**Methods:**

- **Subjects:** Included patients 18 years of age or older, with cIAI, and renal function impairment as defined by the Gault equation (CL\(\text{Cr}\) ≤ 130 mL/min).
- **Microbiological response categories:** Eradication, presumptive eradication, persistence, persistence with decreased susceptibility, presumed persistence, or indeterminate (assessment not possible).
- **Safety:** Safety evaluations in all patients in the ITT population were conducted for safety.
- **Place of Study:** Erovacycline was developed by Tetrapharmaceuticals.

**Table:**

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