Study Population and Demographics
A total of 241 patients were enrolled in the study; patient disposition by study population is shown in Table 1.

<table>
<thead>
<tr>
<th>Table 1. Patient Disposition</th>
<th>PTK 0796</th>
<th>Linezolid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of patients enrolled</strong></td>
<td>111</td>
<td>108</td>
</tr>
<tr>
<td><strong>Number of patients completing treatment</strong></td>
<td>84</td>
<td>78</td>
</tr>
<tr>
<td><strong>Number of patients completing safety evaluations</strong></td>
<td>111</td>
<td>108</td>
</tr>
</tbody>
</table>

**Study Inclusion Criteria:**
- PTK 0796 was the first oral antibiotic in clinical development.
- Adults with cSSSI meeting inclusion and exclusion criteria.
- Patients with severe infections (n=121) or moderate infections (n=120).
- Patients with HIV infection and AIDS (n=7).
- Patients with life expectancy less than 3 months (n=7).
- Patients requiring hemodialysis or peritoneal dialysis (n=18).
- Patients with creatinine clearance <30mL/min (n=14).
- Patients with absolute neutrophil count <500/uL (n=8).
- Patients with a total body weight <40kg or >150kg (n=10).

**Study Exclusion Criteria:**
- Patients with known drug allergy to PTK 0796 (n=3).
- Patients with known drug allergy to linezolid (n=4).
- Patients with baseline renal impairment (n=12).
- Patients with baseline hepatic impairment (n=3).
- Patients with pregnant or breastfeeding (n=1).
- Patients with a history of drug addiction (n=2).
- Patients with a history of alcoholism (n=4).

**RESULTS:**

The targeted indications for PTK 0796 encompass serious acute bacterial infections, either prompting or occurring during hospitalization. These include complicated skin and skin structure infection (cSSSI), ... for initial parenteral therapy in seriously ill patients as well as the option for subsequent oral “step-down” treatment.

**Microbiology:**

MRSA was the most frequent primary pathogen isolated in both PTK 0796 and linezolid groups (Table 9).

**Clinical Efficacy:**

PTK 0796 and linezolid demonstrated comparable efficacy across all five study pathogens (Table 7).

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**TABLE 7. Summary of Clinical Outcome by Population**

**CONCLUSIONS:**

In this Phase 2 study of over 240 adults with cSSSI and skin structure infections, the safety and efficacy of PTK 0796 administered by IV and oral routes was comparable to linezolid (100mg Q12h).

**REFERENCES:**

BacteriaSHA Board II. PTK 0796: In vivo efficacy and safety of two oral antibiotic formulations. In: 16th ICAAC; Chicago: American Society for Microbiology.


