In a phase 2 complicated skin and soft tissue infections (cSSTI) trial conducted early in the course of therapy were consistent with outcomes assessed 10-17 days after completing therapy for patients treated with either omadacycline (OMC; Paratek Pharmaceuticals Inc. Boston, MA) or linezolid.

Paratek Pharmaceuticals Inc. Boston, MA

**ABSTRACT**

A randomized, controlled, investigator-blinded Phase 2 study compared OMC and linezolid for the treatment of complicated skin and skin structure infections. Patients diagnosed with having complicated skin and skin structure infections were randomized on a 1:1 basis to receive either OMC or linezolid for 24-72 hours. Principal inclusion/exclusion criteria included: (a) having received an investigational drug within the past one month prior to enrollment, (b) having received prior treatment for a serious infection with a potentially effective antibiotic, (c) having had an evaluable lesion size on or before the study entry visit, (d) having been immediately prior to the start of dose; not (e) prior enrollment in this protocol.

**RESULTS**

In the OMC and linezolid treatment populations, the clinical response rates 1-7 days after completing therapy were 88.6% (95% CI 96.4% to 93.2%) for OMC and 78.0% (95% CI 67.5% to 86.9%) for linezolid. Mean reductions in maximal lesion dimension among patients who had a baseline lesion dimension of at least 10 cm were 88.3% (95% CI 88.3% to 89.8%) for OMC and 75.9% (95% CI 75.9% to 76.4%) for linezolid. Measurement of lesion size was performed at each evaluation.

**STUDY DESIGN**

This was a randomized, controlled, investigator-blinded Phase 2 study comparing OMC and linezolid for the treatment of complicated skin and skin structure infections. Patients diagnosed with having complicated skin and skin structure infections were randomized on a 1:1 basis to receive either OMC or linezolid for 24-72 hours. Principal inclusion/exclusion criteria included: (a) having received an investigational drug within the past one month prior to enrollment, (b) having received prior treatment for a serious infection with a potentially effective antibiotic, (c) having had an evaluable lesion size on or before the study entry visit, (d) having been immediately prior to the start of dose; not (e) prior enrollment in this protocol.

All subjects were randomized into one of four groups: (A) Extension (Baseline); (B) All at IV Treatments (OMC); (C) All at IV Treatment and At 10-17 days after dose (Test or Cure 2 evaluation). In addition, the blinded investigator was to see each subject daily during the study to assess wound healing and to determine whether to continue current treatment, switch to IV or oral therapy, or discontinue therapy.

At each of the four structured evaluations, the blinded investigator assessed the subject, with particular attention to scoring the final primary site of infection and obtaining cultures. Clinical outcomes were based on a predefined clinical score card, which was used to assess wound healing and to determine treatment outcomes. Post-hoc analyses were conducted to address recently reported in this study had little effect on the magnitude of wound healing observed for either treatment group. At both time points, OMC was associated with a greater mean reduction compared to linezolid. Following 24-72 hours of therapy, OMC had a 2.0% mean reduction in maximal lesion dimension compared to a 0.7% mean reduction for linezolid. At the end of treatment, patients who had received 24-72 hours of OMC had a mean reduction in maximal lesion dimension of 81.5% compared to 63.2% for those who had received 24-72 hours of linezolid.

**CONCLUSION**

Treatment outcomes of cSSTI patients randomized to OMC compared favorably to those measured in linezolid-treated patients. In post hoc analyses conducted to address recently reported in this study had little effect on the magnitude of wound healing observed for either treatment group. At both time points, OMC was associated with a greater mean reduction compared to linezolid. Following 24-72 hours of therapy, OMC had a 2.0% mean reduction in maximal lesion dimension compared to a 0.7% mean reduction for linezolid. At the end of treatment, patients who had received 24-72 hours of OMC had a mean reduction in maximal lesion dimension of 81.5% compared to 63.2% for those who had received 24-72 hours of linezolid.