Background

- Omadacycline (OMC) is a semisynthetic aminomethylcycline antibiotic registered in the United States as a novel intravenous (IV) and oral therapy for several infections.
- OMC is highly active against Gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA) and enterococci.
- OMC has completed phase 3 clinical development as an IV to oral therapy for community-acquired bacterial pneumonia (CABP).
- The OPTIC study was funded by Paratek Pharmaceuticals, Inc.

Study Design and Treatment

- The OPTIC study was a phase 3, randomized, double-blind study comparing OMC (200 mg IV once daily for 7-14 days) to moxifloxacin (MOX) (400 mg daily for 10 days) for the treatment of adults with CABP (PORT Risk Class II).
- N = 774 patients were randomized to receive OMC or MOX.

Results

- Analysis of the microbiological data from the OPTIC study showed that OMC was effective in adult CABP patients across the most frequently isolated pathogens, including methicillin-resistant Staphylococcus aureus (MRSA) and extended-spectrum β-lactamase (ESBL) producers.
- OMC displayed potent activity against Gram-positive aerobes, with 37/204 (18.1%) OMC patients and 34/182 (18.7%) MOX patients having at least one isolate with resistance to ≥ 1 antibiotic.
- Atypical pathogens occurred in 73/204 (35.8%) OMC patients and in 64/182 (35.3%) MOX patients.
- Multidrug-resistant species occurred in 10/204 (4.9%) OMC patients and 7/182 (3.8%) MOX patients.
- Clinical outcomes were analyzed in the microbiologic intent-to-treat (microITT) population defined as all patients in the intent-to-treat population who had at least one positive culture or clinical response.

Analysis Population

- Clinical outcomes were high based on the investigators' assessment at the PTI visit.
- The OPTIC study monitored 5 patients who died during the study, but none of these deaths were considered related to OMC treatment.

Acknowledgments

- The authors wish to thank the patients and investigators involved in the OPTIC study for their contributions.

References

- References are provided in the full report.

Conclusion

- OMC demonstrated promising activity in CABP and was generally well tolerated.
- Further studies are needed to evaluate the long-term efficacy and safety of OMC in CABP patients.