Omadacycline versus Moxifloxacin in the Treatment of Adults with Community-acquired Bacterial Pneumonia (CABP): Efficacy Analysis According to EMA Requirements

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BACKGROUND

- Omadacycline (OMC) is a semisynthetic antibiotic related to the tetracyclines that is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI), and is investigatively marketed as a parenteral agent for the treatment of community-acquired pneumonia (CABP) and hospital-acquired pneumonia (HAP) in the US for the treatment of infections caused by susceptible Gram-positive and Gram-negative bacteria.

RESULTS

- In this Phase 3 study, CABP patients (N = 774) were randomized to receive single-therapy OMC (n = 386) or single-therapy moxifloxacin (MOX; n = 388).
- The study was stratified by receipt of an allowed antibacterial therapy in 72 hours prior to the start of therapy, antibiotic regimen, and geographic region (Eastern Europe, Western Europe/North America, Rest of World).
- Baseline characteristics were well balanced between treatment groups.

METHODS

- The study was a randomized, double-blind, global, multicenter, active comparator-controlled Phase III study. Patients received single-therapy OMC (300 mg IV [91 ≤ Port Score ≤ 130]) or single-therapy MOX (75 mg IV [91 ≤ Port Score ≤ 130]), or placebo (PSSP) within 24 hours prior to first dose of test agent.
- Success was defined as cure from a blood specimen, respiratory specimen, UAT, and/or serology.

CONCLUSIONS

- Omadacycline demonstrated potent and statistically superior activity against common Gram-positive aerobic bacteria and, as expected, the antibiotic was well tolerated. Omadacycline was associated with significantly lower rates of microbial resistance compared with the comparator.

REFERENCES

5. Risk factors for CABP at baseline (ITT population: OMC vs. MOX). Table 5: Overall Clinical Success at the PTE Visit Based on Moxifloxacin. Figure 3: EMA Analysis Study Populations. Figure 4: Clinical Success at PTE Based on Moxifloxacin and OMC Populations. Table 6: Secondary Efficacy Analysis (PRT). Table 7: Subjects with SIRS at baseline and statistically higher clinical success rates observed in all populations.
6. The OPTIC Study was funded by Paratek Pharmaceuticals, Inc. Medical editorial assistance, funded by Paratek Pharmaceuticals, Inc., was provided by Innovative Communications, Inc.

ACKNOWLEDGEMENTS

The authors wish to thank the subjects and investigators involved in this study.

FUNDING AND DISCLOSURES

The OPTIC Study was funded by Paratek Pharmaceuticals, Inc. Medical editorial assistance, funded by Paratek Pharmaceuticals, Inc., was provided by Innovative Communications, Inc.