Pharmacokinetics and Safety of Omadacycline in Patients with Uncomplicated Urinary Tract Infections

J. Scott Overcash, MD; Pouru Bhiwandi, MD; Evan Tzania; Lynne Garrity-Ryan, PhD; Judith Steenbergen, PhD; Steve Bai, PhD; Surya Chitra, PhD; Amy Manley; Steve Villano, MD

Study Site: San Diego, CA, USA; Wake Research, Raleigh, NC, USA; Paratek Pharmaceuticals, Inc., King of Prussia, PA, USA

Sunday - 200

ABSTRACT

AIM: Omadacycline (OMC), an aminomethylcycline antibiotic currently in phase 3 development as a 24-hr single-dose therapy, has been shown to be active against the most common pathogens causing UTIs. This study evaluated 3 dosing regimens of OMC in patients with uncomplicated cystitis (uUTI).

METHODS: This was a randomized, open-label, parallel-group study evaluating 3 dosing regimens of OMC injection (IV) and oral (PO) in patients with uncomplicated symptomatic cystitis. Patients were randomized to receive 1 of 3 OMC regimens for 5 days (Group 1: 200 mg IV on Day 1 then 300 mg PO Q24h; Group 2: 300 mg PO Q12h on Days 1–5; Group 3: 450 mg PO Q24h on Days 1–3 then 300 mg PO Q24h on Days 4–5). The primary end point was the microbiological response at the Per-Subject Early Treatment Failures (PTE) visit. The secondary end point was clinical response at the day 6 (End of Treatment, EOT) visit.

RESULTS: A total of 31 female patients were enrolled and treated; median age, 38 years (range, 19–75 yr); median weight, 72 kg (range, 43–112 kg). Microbiological cure was observed in 75 (54–121) of 31 (25–54) patients. At steady state (on Day 5), the mean amount of OMC excreted in urine over 24 hours was 21.7, 31.5, and 43.6 mg, in Groups 1, 2, and 3, respectively. At steady state (on Day 5), the mean fraction of dose excreted in urine based on the dose assumed to be absorbed ranged between 11.4% and 27.5%. The most common TEAEs were gastrointestinal (GI) including nausea and vomiting. In general, the GI adverse events did not appear to be dose-related.

CONCLUSIONS: OMC may be a useful alternative for uUTIs and warrants evaluation in larger controlled studies for this indication. Future studies are needed to determine the most appropriate dose and dosing regimen.

INTRODUCTION

Uropathogens cause urinary tract infections (UTIs) in both community-acquired and hospital-acquired settings. The most common bacteria causing UTI are E. coli and Proteus mirabilis. Resistance to currently available antibiotics, including fluoroquinolones, is increasing. Omadacycline (OMC) is an aminomethylcycline antibiotic currently in phase 3 development as a 24-hr single-dose therapy, has been shown to be active against the most common pathogens causing UTIs.

REFERENCES


ACKNOWLEDGMENTS

The authors wish to thank the subjects and investigators involved in this study. The study was funded by Paratek Pharmaceuticals, Inc. with support from Paratek Pharmaceutical, Inc., Paratek Pharmaceuticals, Inc., and Paratek Pharmaceuticals, Inc.