INTRODUCTION

Delafloxacin is a new investigational oral and intravenous (IV) fluoroquinolone. Delafloxacin is more active than trovafloxacin against most fluoroquinolone-resistant pathogens. Delafloxacin has good activity against large enterococci organisms that are susceptible to trovafloxacin. Delafloxacin has good activity against many enterococci organisms that are resistant to trovafloxacin. Delafloxacin may be a consideration in antibiotic choices for IVDA patients. Despite the rapid emergence of AMR (antibiotic resistance), delafloxacin retains excellent activity against many pathogens of clinical relevance at concentrations achievable in the presence of interfering drug interactions, which may be a drug of interest for IVDA patients. 

METHODS AND MATERIALS

Study Design

- Phase 3 double-blind, Phase 2a, multicenter studies of DELAFLOXACIN (DLX) in patients with IVDA (N=187) including wounds, burn, major abrasions, or IV site at end of study. IVDA patients less than 16 years of age were excluded. 

- Patients included IVDA patients with treatment of clinical relevance. Delafloxacin was administered BID to all patients. The investigator assessed demographics were randomized in the US. Median total drug exposure was 5.0 days for either treatment (DLX and VAN/AZ). 

- Two Phase 3 studies were conducted to compare the efficacy and safety of IV and oral delafloxacin (DLX) for the treatment of pelvic inflammatory disease (PID) in the IVDA population. 

- This analysis focuses on the populations with significant drug abuse including IVDA.

Demographics and Efficacy

Table 4 displays the most common baseline pathogens in IVDA patients (MITT populations) as well as for the investigator assessed responses at FU and LFU. 

RESULTS

Table 3 displays the 48-hour objective response rates for the primary objective assessed at 48 hours for IVDA patients. These results are presented in Table 2. 

Table 5 displays the overall summary of treatment-emergent adverse events (TEAEs) for IVDA patients. 

SAFETY

IVDA patients, DLX was non-inferior to VAN/AZ for objective response. 85.9% DLX vs 84.8% VAN/AZ (82.6% DLX vs 79.5% VAN/AZ) as well as the assessment of outcome at FUT. 

CONCLUSIONS

- Most common TEAEs among DLX-treated patients were gastrointestinal events, IV site extravasation and/or injection, and headache.

REFERENCES


5. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208611s000lbl.pdf

6. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208610s014lbl.pdf