OUTCOMES IN PATIENTS WITH HISTORY OF CARDIAC OR VASCULAR DISEASE (CV) DURING TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI) WITH DELAFLOXACIN (DLX) VS VANCOMYCIN/AZTREONAM (VAN/AZ)

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INTRODUCTION

Delafloxacin (DLX) is an antibiotic fluoroquinolone recently approved for the treatment of acute bacterial skin and skin structure infections (ABSSSI). Delafloxacin has excelled in vitro activity against Gram-negative pathogens, including Methicillin-resistant Staphylococcus aureus (MRSA) while retaining good activity against Gram-positive organisms.5 DLX was not selected for phase 3 clinical studies as a sole agent due to potential mutation of ADEs that can occur with some antibiotics, like linezolid, tigecycline, or carbapenems.5

METHODS

We conducted two multicenter, double-blind, double-dummy trials (3024 and 3035) comparing the efficacy and safety of DLX monotherapy to VAN/AZ. Patients with complicated skin and skin structure infections (ABSSSI) were randomized 1:1:1 to DLX (300 mg IV BID for the full course), VAN/AZ (1 g IV BID) or placebo. The primary objective was investigator-assessed response at FU 48-72 hours. Key endpoints were investigator-assessed success at FU 48-72 hours.<ref>http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM265455.pdf</ref>

RESULTS

In patients with cardiac or vascular disease, DLX IV/oral was comparable to VAN/AZ in treatment of ABSSSI patients.4,5

CONCLUSION

In patients with cardiac or vascular disease, DLX IV/oral was comparable to VAN/AZ in treatment of ABSSSI patients.4,5

REFERENCES