ABSTRACT

Background: Delafloxacin (DLX), an anionic antibiotic of the fluoroquinolone family, is in development for treatment of skin infections, including MRSA, VRE, and ABO-SEIs. DLX appears well tolerated with limited renal impact.

Conclusions: Delafloxacin has been evaluated in previous Phase 2 trials in patients with ABSSSI. The current study evaluated the safety and efficacy of DLX compared to vancomycin + aztreonam (VAN) in patients with skin infections, including MRSA. Results: DLX had higher objective response rates than VAN. DLX was associated with fewer TEAEs, with a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population. DLX had a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population.

INTRODUCTION

Delafloxacin (DLX) is an investigational anionic antibiotic of the fluoroquinolone family. DLX has demonstrated in vitro activity against a wide range of Gram-positive and Gram-negative bacteria, including MRSA, VRE, and ABO-SEIs. DLX appears well tolerated with limited renal impact. This study evaluated the safety and efficacy of DLX compared to vancomycin + aztreonam (VAN) in patients with skin infections, including MRSA. Results: DLX had higher objective response rates than VAN. DLX was associated with fewer TEAEs, with a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population. DLX had a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population.

METHODS

Study Design: This was a randomized, double-blind, double-dummy, parallel-group, multicenter study conducted in the United States. Patients were randomized 1:1 to receive either DLX (N=331) or VAN (N=329) for the treatment of ABSSSI. Exclusion Criteria: Patients with a history of hypersensitivity to DLX or VAN were excluded from the study. Inclusion Criteria: Patients with ABSSSI were included in the study. Results: This study demonstrated that DLX had higher objective response rates than VAN. DLX was associated with fewer TEAEs, with a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population. DLX had a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population.

RESULTS

PRIMARY EFFICACY AND MICROBIOLOGIC OUTCOMES

PER-PATIENT MICROBIOLOGIC OUTCOMES AT FU

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DELAFLOXACIN/VANCOUMYCIN + AZTREONAM baseline, n (%) Mutation 0 (0.0) 0 (0.0) 0 (0.0) Resistance 0 (0.0) 0 (0.0) 0 (0.0) Isolates 15 (100.0) 12 (100.0) 27 (100.0) MSSA 14 (93.3) 11 (91.7) 25 (92.6) MRSA 1 (6.7) 1 (8.3) 2 (7.4) K. pneumoniae 6 (40.0) 8 (66.7) 14 (51.9) E. coli 7 (46.7) 5 (41.7) 12 (44.4) Other 0 (0.0) 0 (0.0) 0 (0.0) Includes American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population. DLX had a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population.

Secondary endpoints: Delafloxacin demonstrated superior microbiologic response compared to vancomycin + aztreonam, with a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population.

CONCLUSIONS

Delafloxacin (DLX) is an investigational anionic antibiotic of the fluoroquinolone family. DLX has demonstrated in vitro activity against a wide range of Gram-positive and Gram-negative bacteria, including MRSA, VRE, and ABO-SEIs. DLX appears well tolerated with limited renal impact. This study evaluated the safety and efficacy of DLX compared to vancomycin + aztreonam (VAN) in patients with skin infections, including MRSA. Results: DLX had higher objective response rates than VAN. DLX was associated with fewer TEAEs, with a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population. DLX had a lower discontinuation rate than VAN. There was one SAE of acute renal failure for VAN. Inclusion: American Indian, Alaska Native, native Hawaiian or other Pacific Islander, Asian, or other non-Hispanic 5% of the total population.

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RESULTS OF A GLOBAL PHASE 3 STUDY OF DELAFLOXACIN (DLX) COMPARED TO VANCOMYCIN WITH AZTREONAM (VAN) IN ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI)

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