COMPARISON OF DELAFLOXACIN (DLX) AND VANCOMYCIN (VAN) IN THE TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI)

BY AGE AND GENDER IN TWO PHASE 3 TRIALS

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ABSTRACT

Background: Delafloxacin (DLX) is a novel investigational fluoroquinolone with a broad spectrum of activity against Gram-positive and Gram-negative bacteria. The purpose of this study was to compare DLX with vancomycin (VAN) for the treatment of acute bacterial skin and skin structure infections (ABSSSI).

METHODS: Infections were treated in two international, randomized, double-blind, phase 3 trials (Studies 1 and 2) that included 1,510 patients in North America, Asia, Europe, and Latin America. Patients receiving oral/delayed IV treatment received 5-14 days of DLX 300 mg IV followed by DLX 300 mg ORAL, or VAN 1500 mg IV followed by VAN oral. The primary endpoint was investigator-assessed success at FU.

RESULTS: The pooled analysis for the primary endpoint of early objective response demonstrated that DLX IV/oral was non-inferior to VAN in all age and gender groups. The results of the primary endpoint were consistent across all age and gender subgroups.

CONCLUSION: DLX was well tolerated and provided similar efficacy compared to VAN for ABSSSI in adults and was non-inferior to VAN in all age and gender subgroups.

INTRODUCTION

ABSSSI are a major public health problem, with 750,000 reported cases in the United States annually. Delafloxacin (DLX), a novel investigational drug for the treatment of ABSSSI, has demonstrated activity against Gram-positive and Gram-negative pathogens. This study compares DLX with vancomycin (VAN) for the treatment of ABSSSI among adults and by age and gender.

METHODS

Participants: Patients (n = 1,510) were enrolled in two randomized, double-blind, phase 3 trials (Studies 1 and 2) that included patients in North America, Asia, Europe, and Latin America. Patients received 5-14 days of DLX 300 mg IV followed by DLX 300 mg ORAL, or VAN 1500 mg IV followed by VAN oral. The primary endpoint was investigator-assessed success at FU.

RESULTS: The pooled analysis for the primary endpoint of early objective response demonstrated that DLX IV/oral was non-inferior to VAN in all age and gender groups. The results of the primary endpoint were consistent across all age and gender subgroups.

CONCLUSION: DLX was well tolerated and provided similar efficacy compared to VAN for ABSSSI in adults and was non-inferior to VAN in all age and gender subgroups.

REFERENCES