COMPARISON OF SAFETY PROFILE OF DELAFLOXACIN (DLX) VERSUS VANCOMYCIN/AZTREONAM (VAN/AZ) IN THE TREATMENT OF PATIENTS (PTS) WITH ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI): INTEGRATED SAFETY FINDINGS FROM TWO PHASE III STUDIES

G. R. Corey1, D. Hooper2, T. P. Lodise Jr.3, C. Tseng4, S. Cammarata5

1Duke University Medical Center, Durham, NC; 2Infection Control Unit, Massachusetts General Hospital, Boston, MA; 3Albany College of Pharmacy & Health Sciences, Albany, NY; 4Firma Clinical LLC, Hunt Valley, MD; 5Melinta Therapeutics, Lincolnshire, IL

RESULTS

INTRODUCTION

Delafloxacin was recently approved by the FDA for the treatment of infections caused by susceptible organisms due to its activity in vitro against a wide range of pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), methicillin-resistant Staphylococcus epidermidis (MRSE), and vancomycin-intermediate S. aureus (VISA). Delafloxacin is a quinolone antibiotic that targets DNA gyrase and topoisomerase IV enzymes of bacterial DNA replication, thereby inhibiting bacterial DNA synthesis.

STUDY DESIGN OF 3 PHASE III TRIALS

Delafloxacin was compared with other DLX monotherapy to that of IV vancomycin + aztreonam treatment of patients with ABSSSI. DLX is an anionic comparable to VAN/AZ among patients with ABSSSI.

MATERIALS AND METHODS

Study design and population: Two global, double-blind, placebo-controlled phase III studies of adults, aged ≤65 or >65 years were included. The studies were conducted at 399 sites in the US and 470 sites in 35 countries. Patients were randomized to receive either DLX or VAN/AZ intravenously (IV) or intramuscularly (IM) daily for at least 1 day of treatment. Primary safety end points were all data events recorded after the final dose of study drug. The term ‘event’ is defined as an adverse event (AE) occurring with or without causality relationship.

EXPOSURE AND THERAPEUTIC INDEX

Delafloxacin at a dose of 500 mg every 12 hours was well-tolerated in phase I and II studies. The median time to recovery was 6 days for DLX and 7 days for VAN/AZ. The proportions of patients with no increase in adverse events (AEs) and no increase in serious AEs were similar between the two treatment groups.

SPEAKERS \& STUDY-RELATED COMPENSATION

No speakers or study-related compensation were reported.

REFERENCES


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