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Wockhardt's Zaynich[®] (Zidebactam/Cefepime) Receives Favourable Recommendation from CDSCO's Subject Expert Committee for Treatment of Gram-Negative Infections

The Subject Expert Committee (SEC) of the Central Drugs Standard Control Organization (CDSCO), has granted a favourable recommendation for marketing permission of Wockhardt's novel antibiotic, Zaynich[®] (Zidebactam/Cefepime), for the treatment of Gram-negative infections. This positive opinion paves the way for final approval of Zaynich[®] by the Drugs Controller General of India (DCGI).

The recommendation follows a comprehensive review of the product dossier, including non-clinical data, nine Phase 1 studies, a multi-indication Phase 2 study in meropenem-resistant infections, a global Phase 3 study in complicated urinary tract infections and acute pyelonephritis (cUTI/AP), and data from 85 compassionate-use cases.

Developed over 15 years by a team of 150+ scientists across 10 disciplines, Zaynich[®] features a novel β -lactam enhancer-based mechanism, enabling potentially unprecedented coverage of MDR/XDR Gram-negative pathogens prevalent in India. It is among the most comprehensively evaluated antibiotics globally in recent years, with over 100 national and international publications and presentations, the majority from independent experts.

The Zaynich[®] clinical program includes nine Phase 1 studies in the United States and China (nearly 300 subjects), followed by a global Phase 3 study in 530 patients across 64 sites in the United States, Europe, Latin America, China, and India, and a Phase 2 study in meropenem-resistant infections.

In the Phase 3 study, Zidebactam/Cefepime demonstrated superiority over meropenem in combined clinical and microbiological cure, underscoring the impact of its novel mechanism of action. Earlier, it showed over 97% clinical efficacy in a real-world study of meropenem-resistant infections, including hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), bloodstream infections (BSI), complicated intra-abdominal infections (cIAI), and cUTI, conducted across 15 leading tertiary care hospitals in India.

Zaynich[®] also demonstrated strong efficacy in 85 XDR Gram-negative infection cases treated under compassionate use in India, US, Malaysia and France where no safe and efficacious alternatives were available, highlighting the global unmet medical need in the treatment of resistant Gram negative infections, and the potential of Zaynich[®] to address it.

The Clinical and Laboratory Standards Institute (CLSI) has granted Zidebactam/Cefepime an investigational susceptible breakpoint of 64 mg/L, indicating its potential to comprehensively cover clinically important XDR Gram-negative pathogens in critically ill patients.

A New Drug Application (NDA) in the United States and a Marketing Authorisation Application (MAA) in the European Union for Zidebactam/Cefepime have already been submitted and are currently in the advanced stages of review.

PRESS RELEASE



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About Wockhardt's Antibiotic Discovery portfolio

Over the period of 25 years, Wockhardt has focused its drug discovery efforts in the area of discovering novel medicines for multi-drug resistant infections. This has resulted in a portfolio of 6 products at various stages of clinical development and commercialization, each of which have been granted Qualified Infectious Disease Product status by the US FDA.

DRUG DISCOVERY PROGRAMME

USFDA QIDP STATUS : 6 ANTI-BACTERIALS