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CDSCO grants marketing authorisation to Wockhardt's drug ZAYNICHÂ® for treatment of complicated UTIs

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For the treatment of pyelonephritis with concurrent Gram-negative bacteremia

APPROVED

Mumbai-based Wockhardt has announced that the Central Drugs Standard Control Organisation (CDSCO) has granted authorisation for the import and marketing of its indigenously discovered and developed, first-in-class breakthrough antibiotic, Zaynich® (Zidebactam / Cefepime) in India.

The approval is for the treatment of adult patients (≥18 years) with complicated urinary tract infections (cUTI), including pyelonephritis, as well as cases with concurrent Gram negative bacteremia.

The approval is supported by results from the pivotal ENHANCE-1 study, a multinational, randomized, double-blind Phase 3 clinical trial evaluating the efficacy and safety of Zaynich® compared with meropenem in patients with cUTI, including pyelonephritis.

ZAYNICH® is an injectable antibiotic comprising of a β -lactam enhancer antibiotic, Zidebactam and Cefepime, a cephalosporin antibacterial drug. Zidebactam selectively inhibits penicillin-binding protein-2 (PBP2) while Cefepime primarily targets penicillin-binding protein-3 (PBP3) in Gram negative bacterial pathogens. Cefepime and zidebactam work together by binding to multiple PBPs, leading to bacterial killing.

ZAYNICH has also received Qualified Infectious Disease Product (QIDP) and Fast Track designations from the US FDA.