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Wockhardt's Fifth Novel Antibiotic, Foviscu[®] (WCK 4282), Matches Gold-Standard Meropenem in pivotal Phase 3 Trial as First-Line Therapies Fail Against Rising Resistance

Wockhardt announced that its novel intravenous antibiotic Foviscu[®] (WCK 4282) has successfully met the primary endpoint in a Phase 3 clinical trial in patients with complicated urinary tract infections (cUTI) and acute pyelonephritis caused by Gram-negative bacteria, including extended-spectrum β -lactamase (ESBL)-producing pathogens. ESBL enzymes make many commonly used antibiotics ineffective and are a major cause of difficult-to-treat hospital infections.

With this milestone, Foviscu[®] becomes the fifth proprietary antibiotic from Wockhardt to complete a registration-enabling Phase 3 study, following Emrok[®], Emrok O[®], Miqna[®], and Zaynich[®], further strengthening Wockhardt's leadership in antibiotic discovery space.

In a randomized, double-blind Phase 3 study, Foviscu[®] was directly compared with meropenem, a "last-line" gold-standard carbapenem widely used for severe drug-resistant Gram-negative infections. At the Test-of-Cure visit, Foviscu[®] achieved a high clinical cure rate of 93.23% versus 92.31% with meropenem, thereby meeting the primary endpoint and demonstrating therapeutic equivalence with a similarly well-tolerated safety profile. This is the first Phase 3 head-to-head trial of an antibiotic specifically developed for ESBL infections compared with meropenem.

ICMR data show a high burden of ESBLs and rising resistance to commonly used antibiotics such as piperacillin/tazobactam and cefoperazone/sulbactam, increasingly forcing clinicians to rely on carbapenems (meropenem) and thereby accelerating carbapenem resistance. By providing an effective alternative, Foviscu[®] has the potential to reduce carbapenem use and strengthen antibiotic stewardship to curb antimicrobial resistance. Currently, approximately 65 lakh treatment courses of meropenem, piperacillin/tazobactam, and cefoperazone/sulbactam are used annually in India.

Foviscu[®] underwent a combined Phase 2 and Phase 3 program which enrolled 323 hospitalized cUTI and AP patients (Phase 2: 60; Phase 3: 263). The most common causative pathogens were Escherichia coli, Klebsiella spp., Enterobacter spp., and Pseudomonas spp. More than half of the Enterobacterales isolates (51.4%) were ESBL-positive, and 33.8% of Gram negatives were resistant to cefepime, underscoring the urgent need for stronger first-line treatment options in India, where ESBL prevalence is high.

About Foviscu[®] (WCK 4282)

Foviscu[®] is globally the only scientifically developed single-vial dosage form that combines pharmacodynamically optimized and clinically validated doses of tazobactam 2 g and cefepime 2 g, enabled by proprietary technology designed to ensure safety.

WCK 4282 has been extensively evaluated through a comprehensive global program covering clinical development, pharmacokinetics/pharmacodynamics (PK/PD), antimicrobial susceptibility testing methods, and microbiology. Phase 1 and renal impairment studies were conducted in The Netherlands, PK/PD studies in the US, Europe and India, and microbiology studies on global bacterial isolates in the US and India. Its

PRESS RELEASE



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strong activity against ESBL-producing pathogens has been documented in several peer-reviewed publications in leading international journals. WCK 4282 has been accorded qualified infectious disease product (QIDP) designation by US FDA. The combined Phase 2/3 trial was partly supported by National Biopharma Mission (NBM), an initiative of Department of Biotechnology, Government of India.

About Wockhardt's Drug 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