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PRESS RELEASE

Indian drug regulator grants marketing authorization to Wockhardt's breakthrough antibiotic, ZAYNICH® (Zidebactam/ Cefepime), for treatment of complicated urinary tract infections including pyelonephritis with concurrent Gram-negative bacteremia

Mumbai, India, May 28, 2026 – Wockhardt Ltd. today announced that the Central Drugs Standard Control Organisation (CDSCO) has granted authorization 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 (NCT04979806), 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. Patients were randomized in a 2:1 ratio to receive Zaynich® or meropenem. In this study, Zaynich® demonstrated statistical superiority over meropenem for the primary composite endpoint of clinical cure and microbiological eradication at the test-of-cure (TOC) visit. The primary endpoint was achieved in 89% (250/281) of patients treated with Zaynich®, compared to 68.4% (93/136) in the meropenem arm, with a treatment difference of 20.6% in favour of Zaynich®. The TOC assessment was conducted approximately 10 days after completion of therapy.

Notably, among patients with concomitant bacteremia at baseline, composite response rates at TOC were 89% (16/18) in the Zaynich® arm versus 44% (4/9) in the meropenem arm, underscoring its potential in severe and high-risk infections.

Prior to the Phase 3 program, Zaynich® was evaluated across nine Phase 1 studies and a Phase 2 clinical study involving patients with documented meropenem-resistant Gram-negative infections. This Phase 2 study, conducted across 15 leading tertiary care hospitals in India, demonstrated over 97% clinical efficacy across serious infections including hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), bloodstream infections (BSI), complicated intra-abdominal infections (cIAI), and cUTI.

These findings highlight the potential of Zaynich® as a life-saving therapeutic option, particularly in carbapenem-resistant infections where current treatment options such as colistin and polymyxins are limited by significant toxicity and suboptimal efficacy. Importantly, Zaynich® is uniquely positioned to address metallo-β-lactamase (MBL)-mediated resistance, one of the most prevalent and challenging resistance mechanisms in India.

In recognition of its broad-spectrum potential, the Clinical and Laboratory Standards Institute has assigned Cefepime/Zidebactam an investigational susceptible breakpoint of 64 mg/L, supporting its potential to cover clinically important extensively drug-resistant (XDR) Gram-negative pathogens in critically ill patients.

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About ZAYNICH®

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.

Under compassionate use, Zaynich® has demonstrated strong clinical efficacy in 85 cases of Extensively Drug Resistant (XDR) Gram-negative infections across India, the United States, Malaysia, and France, where no safe and effective alternatives were available. These outcomes underscore the significant global unmet need in resistant Gram-negative infections and the potential of Zaynich® to address this challenge.

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

Zaynich® has also received Priority Review, Fast Track and Qualified Infectious Disease Product (QIDP) designations by US FDA for Complicated Urinary Tract Infections (cUTI), Complicated Intra-Abdominal Infections (cIAI), Hospital-Acquired Bacterial Pneumonia (HABP) / Ventilator-Associated Bacterial Pneumonia (VABP).

About Wockhardt

Wockhardt is a research based global pharmaceutical and biotechnology company focused on developing innovative anti-infective solutions. With a legacy of scientific excellence and a mission to combat antimicrobial resistance, Wockhardt pioneers next-generation therapies for a healthier world. This commitment has resulted in a pipeline of six antibiotics at various stages of clinical development and commercialization; three of them target infections caused by Gram-Negative pathogens and three those by Gram-Positives. All six antibiotics have been granted Qualified Infectious Disease Product (QIDP) designation by the US FDA.

Wockhardt employees ~3200 people and 27 nationalities, with presence in India, the UK, the U.S., Ireland, Switzerland, France, Mexico, Russia, and many other countries. It has manufacturing and research facilities in India & the UK, and a manufacturing facility in Ireland. Wockhardt has a significant presence in Europe and India, with 78% of its global revenues coming from international businesses.