PRESS RELEASE

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Wockhardt Receives U.S. FDA Approval for ZAYNICH™ (cefepime and zidebactam), a Novel Intravenous Antibiotic for the Treatment of Adult Patients with Complicated Urinary Tract Infection Including Pyelonephritis

ZAYNICH™ is a multi- penicillin-binding protein targeting combination of the 4th generation cephalosporin cefepime and zidebactam working synergistically against the most challenging multidrug-resistant Gram-negative bacteria

In the Phase 3 ENHANCE-1 clinical trial, ZAYNICH™ demonstrated higher combined clinical cure and microbiologic response (composite endpoint) at the test of cure (TOC) visit versus meropenem, 89.0% vs 68.4% respectively and was generally well tolerated

More than 2.8 million antimicrobial-resistant infections occur each year in the U.S., resulting in more than 35,000 deaths[1]

MUMBAI & SHORT HILLS, NEW JERSEY (May 30, 2026) – Wockhardt today announced that the U.S. Food and Drug Administration (FDA) has approved ZAYNICH™ (cefepime and zidebactam), a novel intravenous antibiotic for the treatment of adults with complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible Gram-negative pathogens. ZAYNICH™ previously received Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA.

"The threat of drug-resistant infections is an escalating crisis, leaving clinicians with fewer tools to treat patients facing these aggressive pathogens. The FDA approval of ZAYNICH™ is a monumental step forward in validating a new option for these underserved populations," said **Dennis Deruelle, MD, FHM, Chief Medical Officer at Wockhardt**. "This milestone underscores our commitment to addressing critical unmet needs and offers a profound sense of hope to the families we are working to serve."

"This approval is a significant realization of our mission to provide patients with novel antibiotics that help to address one of the most urgent global health threats—antimicrobial resistance," [2] said **Dr. Habil F. Khorakiwala, Founder and Chairman of Wockhardt Group**. "Furthermore, ZAYNICH™ is the first New Chemical Entity fully developed and commercialized by an Indian pharmaceutical company to receive an FDA approval, representing a historic milestone not only for Wockhardt, but for the Indian pharmaceutical industry."

ZAYNICH™, unlike most other beta-lactam combinations, targets multiple penicillin binding proteins (PBP 1a/b, 2 and 3) simultaneously. This unique, multi-target synergy provides bactericidal activity against the most challenging drug-resistant Gram-negative bacteria for which there are currently very limited treatment options.

"Multidrug-resistant bacterial infections are a substantial burden for patients and the healthcare system, as patients with these infections typically require longer, more intensive care, and are at increased risk of life-threatening complications," explained **Keith Kaye, MD, MPH, Professor of Medicine and Division Chief**

for Infectious Diseases at Rutgers Robert Wood Johnson Medical School. "There is an ongoing need for new antibiotics to combat these drug-resistant pathogens, and we are pleased that this approval means patients will soon have an exciting unique option that is urgently needed in the US and worldwide."

cUTI is responsible for over 600,000 hospitalizations in the U.S. annually. A growing number of cUTIs are caused by antimicrobial resistant bacteria, including multidrug-resistant bacteria, a leading cause of bacteremia and associated with significant morbidity and mortality and a burden on the health care system.[3]

The FDA approval was based, in part, on the results from ENHANCE-1, a Phase 3, randomized, double-blind, multicenter study which evaluated the efficacy, safety and tolerability of ZAYNICH™ compared with meropenem in the treatment of hospitalized adults with cUTI or acute pyelonephritis (AP). ZAYNICH™ demonstrated efficacy at the primary endpoint, achieving a composite clinical cure and microbiological response rate of 89.0% versus 68.4% for meropenem Treatment difference 20.6% (95% CI; 12.3, 29.5). ZAYNICH™ was generally well tolerated in the phase 3 study. The study enrolled 530 patients from the U.S., Europe, LATAM, China and India, and spanned across 64 sites.

ZAYNICH® was approved by the Drugs Controller General of India (DCGI) on May 27, 2026. Wockhardt has also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency.

About ZAYNICH™ (cefepime and zidebactam) for Injection

ZAYNICH™ (cefepime and zidebactam) is an injectable antibiotic comprising of cefepime, a cephalosporin antibacterial drug and zidebactam, a non-β-lactam antibacterial and β-lactamase inhibitor. Cefepime primarily targets penicillin-binding protein-3 (PBP3) and PBP1a/b in Enterobacterales and PBP3 in other Gram-negative bacterial pathogens, while zidebactam selectively inhibits penicillin-binding protein-2 (PBP2). Cefepime and zidebactam synergistically work together by binding multiple PBPs, leading to bacterial killing. This synergy occurs even in the presence of β-lactamases, including metallo- β-lactamases (MBLs), which are not inhibited by zidebactam, and other non-enzymatic cefepime resistance mechanisms, such as hyper-efflux and downregulation of outer membrane porin channels.

ZAYNICH™ was granted Priority Review, Fast Track and Qualified Infectious Disease Product designations for the Complicated Urinary Tract Infections (cUTI), Complicated Intra-Abdominal Infections (cIAI), Hospital-Acquired Bacterial Pneumonia (HABP)/Ventilator-Associated Bacterial Pneumonia (VABP).

ZAYNICH™ has also been made available through expanded access programs in multiple countries including the U.S. for patients with limited treatment options.

INDICATION AND USAGE

Complicated Urinary Tract Infections, Including Pyelonephritis

ZAYNICH™ is indicated for the treatment of adult patients with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Enterobacter cloacae* complex, and *Pseudomonas aeruginosa*.

Usage to Reduce Development of Drug-Resistant Bacteria

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZAYNICH™ and other antibacterial drugs, ZAYNICH™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ZAYNICH™ is contraindicated in patients with a known history of serious hypersensitivity to the components of ZAYNICH™ (cefepime and zidebactam) or other beta-lactam antibacterial drugs.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis, have been reported in patients treated with ZAYNICH™. Serious and occasionally fatal hypersensitivity reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before therapy with ZAYNICH™ is instituted, carefully inquire about previous hypersensitivity reactions to cefepime, cephalosporins, penicillins, or other beta-lactams because cross-hypersensitivity among beta-lactam antibacterial drugs has been reported. If an allergic reaction to ZAYNICH™ occurs, discontinue the drug and institute appropriate supportive measures.

Neurotoxicity: Neurotoxicity has been reported during treatment with cefepime, a component of ZAYNICH™, including life-threatening or fatal occurrences of the following: encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), aphasia, myoclonus, seizures, and nonconvulsive status epilepticus. Most cases occurred in patients with renal impairment who did not receive appropriate dosage adjustment. If neurotoxicity associated with ZAYNICH™ therapy occurs, discontinue ZAYNICH™ and institute appropriate supportive measures.

***Clostridioides difficile*-Associated Diarrhea (CDAD):** CDAD has been reported with the use of nearly all antibacterial agents including ZAYNICH™ and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued.

Positive Direct Coombs' Tests: Positive direct Coombs' tests with or without hemolysis have been reported during treatment with cefepime, a component of ZAYNICH™. In patients who develop hemolytic anemia, discontinue the drug and institute appropriate therapy.

Prolonged Prothrombin Time: Decrease in prothrombin activity has been reported for many cephalosporins including cefepime, a component of ZAYNICH™. Those at risk include patients with renal or hepatic impairment or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy. Prothrombin time should be monitored in patients at risk, and exogenous vitamin K should be administered as indicated.

Development of Drug-Resistant Bacteria: Prescribing ZAYNICH™ in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Interactions with Urine Glucose Testing: The administration of cefepime, a component of ZAYNICH™, may result in a false-positive reaction for glucose in the urine when using some methods (e.g., Clinitest™ tablets). It is recommended that glucose tests based on enzymatic glucose oxidase reactions be used.

ADVERSE REACTIONS

The most common adverse reactions occurring in ≥2% of patients receiving ZAYNICH™ were diarrhea, hypertension, headache, and hypokalemia.

Please see full Prescribing Information for ZAYNICH™.

About Wockhardt

Wockhardt is a 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 employs around 3,200 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. For more information, visit https://www.wockhardt.com/.

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[1] Centers for Disease Control and Prevention. (2019). *Antibiotic resistance threats in the United States, 2019*. U.S. Department of Health and Human Services. Retrieved May 27, 2026, from https://www.cdc.gov/antimicrobial-resistance/media/pdfs/2019-ar-threats-report-508.pdf

[2] Centers for Disease Control and Prevention. (2025, January 31). *About antimicrobial resistance*. Retrieved May 27, 2026, from https://www.cdc.gov/antimicrobial-resistance/about/index.html

[3] Marantidis, J., & Sussman, R. D. (2023). Unmet needs in complicated urinary tract infections: Challenges, recommendations, and emerging treatment pathways. *Infection and Drug Resistance, 16*, 1391–1405. https://doi.org/10.2147/IDR.S382617 Retrieved May 27, 2026, from https://pubmed.ncbi.nlm.nih.gov/36937144/