

PRESS RELEASE**WOCKHARDT** | **LIFE WINS****Mumbai, 1st October, 2025**

Wockhardt Submits New Drug Application to U.S. FDA for Zidebactam-Cefepime (WCK 5222) for Treatment of Serious Gram-Negative Infections

Wockhardt today announced the submission of New Drug Application (NDA) to the U.S. Food and Drug Administration (US FDA) for its novel antibacterial agent Zidebactam-Cefepime injection (WCK 5222, **ZAYNICH™**). The NDA seeks approval for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, with or without concurrent bacteremia caused by Gram-negative bacteria including multidrug-resistant (MDR). In US and EU, more than 8 Million cUTI cases are reported every year, reflecting the global burden of Gram negative infections.

This milestone marks the first-ever NDA submission to the U.S. FDA for a drug, fully discovered and developed by an Indian pharmaceutical company, a momentous achievement for Indian innovation.

Amidst the escalating global crisis of antimicrobial resistance (AMR), Zidebactam-Cefepime represents a first-in-class β -lactam enhancer and β -lactam combination, introducing a novel mechanism of action to combat some of the most difficult-to-treat infections particularly those that remain unresponsive to approved antibiotics, including those that are recently approved. Clinical and non-clinical studies have demonstrated its potent activity against multi-drug resistant (MDR) and extreme drug resistant (XDR) Gram-negative pathogens, including those harbouring NDM carbapenemases and PBP mutations. A Phase II study undertaken has demonstrated its efficacy against diverse carbapenem-resistant infections.

The NDA submission follows the successful completion of a pivotal Phase III global clinical trial (ENHANCE 1), conducted across 64 sites in India, USA, Bulgaria, Estonia, Lithuania, Poland, Slovakia, Mexico, and China. The program is supported by a robust clinical development package, including nine Phase I studies conducted in the U.S. and China, a Phase II study conducted in India and a multinational Phase III trial evaluating efficacy in cUTI, including pyelonephritis.

Zidebactam-cefepime has been granted qualified infectious disease product (QIDP) and Fast Track Designation by US FDA.

Gram-negative infections have become increasingly difficult to treat due to wide spread resistance to multiple classes of antibiotics. Zaynich™ has the potential to treat a broad range of infections caused by MDR or XDR pathogens including Enterobacterales and Pseudomonas aeruginosa and A. baumannii.

About Zidebactam-Cefepime (WCK 5222 / Zaynich™)

Zaynich™, combination of Zidebactam & Cefepime, is Wockhardt's novel proprietary antibiotic, targeted towards multi-drug resistant Gram-negative infections. Zaynich™ is a novel β -lactam enhancer mechanism of action drug, which overcomes all the clinically important resistance mechanisms in Gram negative

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pathogens including tough-to-treat *Pseudomonas*, *Stenotrophomonas*, *Acinetobacter* and *Klebsiella*. Such spectrum of activity of Zaynich™ has been documented through >100 publications/presentations, majority from US and EU based independent experts/organizations.

About Wockhardt

Wockhardt is a research based global pharmaceutical and biotech company. For over 27 years, Wockhardt has been at the forefront of antibiotic innovation, focusing its drug discovery efforts on combating multi-drug resistant infections. This commitment has resulted in pipeline of 6 antibiotics at various stages of clinical development and commercialization— 3 of them are Gram Negative and 3 Gram Positive effective against untreatable “Superbugs”. All the 6 antibiotics have been granted Qualified Infectious Disease Product (QIDP) designation by the US FDA. Three of these novel antibiotics are already approved for clinical use, while two more are in the final stages of development. It has a comprehensive Drug Discovery team and clinical organisation.

Wockhardt is employing around ~2,900 people and 27 nationalities with presence in UK, Ireland, Switzerland, France, Mexico, Russia and Emerging markets. It has manufacturing and research facilities in India & UK and a manufacturing facility in Ireland. Wockhardt has a significant presence in Europe and India, with ~77% of its global revenues coming from international businesses.

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