

Mumbai, 31st December 2025

European Medicines Agency Grants Accelerated Assessment to WCK 5222

The European Medicines Agency (EMA) has informed Wockhardt that **WCK 5222** (combination of Zidebactam 1g + Cefepime 2g) is eligible for **Accelerated Assessment**, following a pre-submission meeting with the EMA review team.

The Accelerated Assessment designation reflects EMA's view that WCK 5222 has the potential to address an unmet medical need by providing an effective therapeutic option for the treatment of following serious and life-threatening infections, particularly those caused by multi-drug-resistant (MDR) and extremely drug-resistant (XDR) Gram negative pathogens.

- **Complicated urinary tract infections (cUTI)**, including pyelonephritis
- **Hospital-acquired pneumonia (HAP)**, including ventilator-associated pneumonia (VAP)
- **Complicated intra-abdominal infections (cIAI)**
- **Treatment of patients with bacteraemia** occurring in association with, or suspected to be associated with, cUTI/acute pyelonephritis, HAP/VAP, or cIAI
- **Treatment of infections due to aerobic Gram-negative organisms** in adult patients with limited treatment options

During the scientific review discussions, EMA noted the **novel β -lactam enhancer mechanism of action** of WCK 5222 and its relevance in overcoming plethora of resistance mechanisms in Gram-negative bacteria. Based on the totality of available non-clinical, clinical and pharmacokinetic-pharmacodynamic (PK-PD) data, **EMA has concurred that WCK 5222 is eligible for accelerated assessment** pursuant to Article 14 (9) of Regulation (EC) no 726/2004.

If approved, the proposed breadth of indications would support the use of WCK 5222 across a wide range of serious infections and contribute to addressing the growing public health challenge of antimicrobial resistance. WCK 5222 represents the **first New Chemical Entity (NCE) discovered and developed in India to be submitted for pan-European marketing authorisation**, reflecting the advancement of an India-initiated global antimicrobial innovation efforts.

About Zaynich® (Zidebactam/Cefepime, WCK 5222)

Zaynich® is a novel, proprietary antibiotic developed by Wockhardt, combining Zidebactam and Cefepime to combat multi-drug resistant Gram-negative infections. The drug recently completed a global, pivotal Phase III clinical trial, which will support its marketing authorization across international markets. The New Drug Application (NDA) for Zaynich® has been filed and accepted by the United States Food and Drug Administration (USFDA). The application for Marketing Authorization has also been filed with the Indian regulatory authorities. Prior to this, multiple Phase I clinical pharmacology studies involving the Zidebactam/Cefepime combination were successfully conducted in the United States. Zaynich® has also completed a multi-indication clinical study in India, specifically targeting carbapenem-resistant infections. To date, more than 50 patients in India and the U.S. suffering from highly resistant infections have been treated with Zaynich® under compassionate use programs.

About Wockhardt's Drug Discovery portfolio

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 a strong pipeline of six antibiotics at various stages of clinical development and commercialization—all of which have been granted

Qualified Infectious Disease Product (QIDP) designation by the U.S. FDA. Three of these novel antibiotics are already approved for clinical use, while two more are in the final stages of development.

Wockhardt is employing around ~2900 people and 27 nationalities with presence in USA, UK, Ireland, Switzerland, France, Mexico, Russia and many other countries. 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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