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Zaynich[®] (Zidebactam/Cefepime, WCK 5222) achieves over 97% Efficacy in Clinical Study for serious infections caused by Meropenem-Resistant Gram-Negative Pathogens

In a ground-breaking clinical study, Zaynich[®] (Zidebactam/Cefepime, WCK 5222) demonstrated over 97% clinical efficacy in treating seriously ill patients with infections caused by carbapenem-resistant (including meropenem-resistant) Gram-negative pathogens. The study design was unique as it encompassed a range of severe infections, including hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), bloodstream infections (BSI), complicated intra-abdominal infections (cIAI), and complicated urinary tract infections (cUTI). 17% of these patients also had concurrent BSI thus further escalating the therapeutic challenge.

The overall clinical efficacy of Zaynich[®] across indications was 98% at the test-of-cure (TOC), which was 7-10 days after completion of treatment, while it was 100% for BSI, HABP/VABP & cIAI and 97.3% for cUTI. Notably, Zaynich[®] also demonstrated high pathogen eradication rates (microbiological cure) including for tougher-to-treat HABP/VABP (91%) and BSI patients (100%).

Taking into account the results from this clinical study as well as several patients successfully treated under compassionate use in India and US, lives of more than 100 critically ill patients, infected with life-threatening XDR Gram-negative infections have been saved with administration of Zaynich[®].

Conducted across 15 top-rated tertiary care hospitals nationwide, this clinical study exclusively involved patients with confirmed carbapenem-resistant (including meropenem-resistant) infections, identified through advanced molecular rapid diagnostic technologies. The infecting pathogens were a diverse range of extensively drug-resistant (XDR) Gram-negatives such as *Acinetobacter* spp., *Pseudomonas* spp., *Klebsiella* spp., and *E. coli*. Treatment durations ranged from 7 to 21 days. The study protocol was duly approved by Drugs Controller General of India (DCGI).

This study underscores the potential of Zaynich[®] as a life-saving antibiotic, particularly for carbapenem-resistant infections. Current highly compromised treatment options are colistin and polymyxins, which are marred with significant toxicity and efficacy limitations.

The significance of these findings is amplified by the world-wide threat posed by antimicrobial resistance. Zaynich[®] targets all the Gram negative pathogens identified as critical priorities by the U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).

About Zaynich[®] (Zidebactam/Cefepime, WCK 5222)

Zaynich[®], combination of Zidebactam & Cefepime, is Wockhardt's novel proprietary antibiotic, targeted towards multi-drug resistant Gram-negative infections. It is currently nearing completion of multi-national Phase III study which would support its registration/marketing authorization globally. Earlier, several Phase I studies including clinical pharmacology studies with zidebactam/cefepime were conducted in US. As India has significantly higher rates of meropenem-

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resistant infections, Phase II study was conducted in India to generate a robust evidence of Zaynich[®]'s effectiveness in overcoming the challenge posed by AMR.

About Wockhardt's New 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.

About Wockhardt

Wockhardt is a research based Global Pharmaceutical and Biotech company. Wockhardt is the only company in the world where USFDA has given QIDP Status (Qualified Infectious Disease Product) for 6 of our Anti-bacterial discovery programmes – 3 of them are Gram Negative and 3 Gram Positive effective against untreatable "Superbugs". It has a comprehensive Drug Discovery team and clinical organisation.

Wockhardt is employing around ~2600 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, USA & UK and a manufacturing facility in Ireland. Wockhardt has a significant presence in USA, Europe and India, with 79% of its global revenues coming from international businesses.