PRESS RELEASE

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Zidebactam/Cefepime, WCK 5222 Update

- **Zidebactam/Cefepime, an investigational antibiotic, belongs to a new class known as "β- lactam enhancer" and is under investigation to treat complicated urinary tract infections, including acute pyelonephritis.**
- **Phase III Clinical trial for Zaynich (Zidebactam/Cefepime) is progressing as per plan and we expect this to be concluded by Q1, 2025. As on 27th May, 392 patients have been recruited in the trial.**
- **Zaynich (Zidebactam/Cefepime) Phase III Clinical trial is a global multi-centric trial involving 64 centres in 9 countries including US, Europe, India, China, Latin America.**
- **We continue to receive the requests for Zidebactam/Cefepime for compassionate use for treating difficult-to-treat and complicated cases such as serious blood stream infections, hospital and ventilator- associated bacterial pneumonia, osteomyelitis and intra-abdominal infections in cancer and transplant patients. So far we have supplied Zidebactam/Cefepime to 30 patients for compassionate use with range of life-threatening infections as described below:**
  - **11 patients with Hospital/ventilator Acquired Pneumonia infected with pan-drug resistant pathogens, several of them in septic shock**
  - **2 patients of serious Bloodstream infection in septic shock**
  - **8 patients of Osteomyelitis failed to resolve with any of the available antibiotic options even when treated for longer duration**
  - **4 patients of complicated Urinary tract infection with severe renal impairment**
- **We are happy to report 100% clinical cure rate in all these 30 critically ill patients with diverse life-threatening, extreme-drug-resistant Gram-negative infections under compassionate use.**

During last one year, global Phase 3 clinical stage, India-discovered, Zidebactam/Cefepime was successfully used to treat 30 critically-ill patients, several with cancer and organ transplant, across 24 leading Indian tertiary care hospitals under compassionate use. These patients were grappling with a spectrum of challenging life-threatening infections, including hospital-acquired/ventilator-associated pneumonia, empyema (collection of pus in lungs), bloodstream infections, urosepsis, intra-abdominal infections, necrotizing fasciitis (flesh-eating bacterial infection) , and osteomyelitis caused by variety of extreme-drug resistant (XDR) Gram-negative pathogens, including Pseudomonas, Klebsiella, E. coli, Acinetobacter, and Serratia. Disturbingly, these pathogens were resistant to last-resort antibiotics such as meropenem, as well as newer antibiotics specifically developed to treat resistant Gram-negative pathogens such as ceftazidime/avibactam, ceftolozane/tazobactam, imipenem/relebactam, and some even to cefiderocol. Prior to seeking compassionate use of Zidebactam/Cefepime, medical practitioners attempted treating these patients with colistin or polymyxin B, which unfortunately led to severe nephrotoxicity and neurotoxicity without resolving the infections.

As a last resort, under compassionate use approval from Central Drugs Standard Control Organisation (CDSCO), Zidebactam/Cefepime was administered to these patients, with treatment durations ranging from one week to eleven weeks. Remarkably, within 1-2 weeks of initiating Zidebactam/Cefepime therapy, patients showed significant clinical improvement, and by the end of treatment, they were clinically and microbiologically cured of these recalcitrant infections. Zidebactam/Cefepime was tolerated well even when administered up to 11 weeks which was required for unyielding infections such as osteomylietis.

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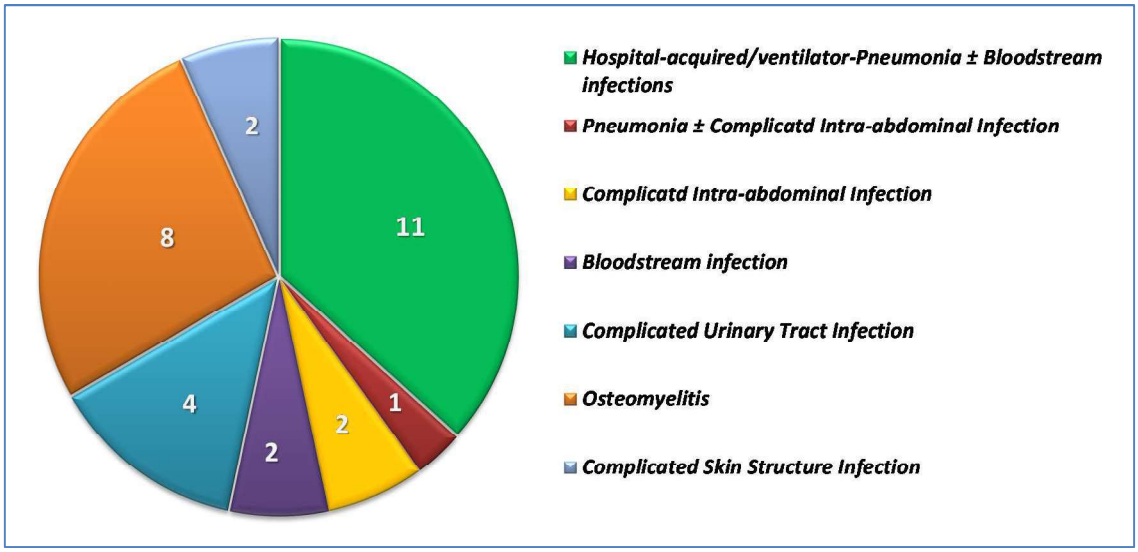
It's noteworthy that most of these patients had underlying complications such as cancer, kidney transplant, liver transplant, bilateral lung transplant, bone marrow transplant, immune suppression, and severe renal impairment. Twenty patients had previously failed to respond to antibiotic combinations such as ceftazidime/avibactam + aztreonam + polymyxin B/colistin, while colistin/polymyxin B treatment had proven ineffective in ten patients. Additionally, eight patients were in septic shock prior to the initiation of Zidebactam/Cefepime therapy.

Currently, Zidebactam/Cefepime is undergoing a multinational Phase 3 study, which is expected to facilitate its global registration and marketing authorization. Earlier, several Phase 1 studies, including clinical pharmacology studies, were conducted in the United States.

Wider dissemination of MDR/XDR pathogens in Indian hospitals and also globally underscores the therapeutic challenge faced by the doctors and highlights urgent need of 'high-efficacy' antibiotics to manage such life-threatening infections in ICUs.

WCK 5222 used for various types of life-threatening infections - Compassionate use



About Wockhardt

Wockhardt is a research based Global Pharmaceutical and Biotech company. Wockhardt's New Drug Discovery programme has focussed on unmet need of Anti-bacterial drugs that are effective against the menace of untreatable superbugs. 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 77% of its global revenues coming from international businesses.