

Mumbai, 28th June 2024

Successful Use of Investigational Antibiotic, Zaynich (Zidebactam/Cefepime- WCK 5222) to Treat a Cancer Patient in US with Chronic Bilateral Thigh Infection Caused by an Extreme-Drug Resistant Pseudomonas

Recently, a young immune-compromised cancer patient, who has been hospitalized for nearly 9 months at Children's Hospital of Orange County, University of California Irvine School of Medicine was successfully treated with 4 weeks of Zaynich (Zidebactam/Cefepime- WCK 5222) for chronic thigh infection under compassionate use, enabling doctors to resume chemotherapy. During the long hospital stay, patient grappled with multiple rounds of infections necessitating extensive use of several antibiotics. With no treatment options left, the hospital sought the access to Zaynich (Zidebactam/Cefepime- WCK 5222) under a provision termed as 'Expanded Access IND' granted by the US FDA. This case marks the first instance in the US where Zaynich (Zidebactam/Cefepime- WCK 5222) has been employed to combat a complex infection caused by extreme-drug resistant Pseudomonas.

The patient had a complicated clinical history of Acute Myeloid Leukemia (blood and bone-marrow cancer), Extracorporeal Membrane Oxygenation support, Chronic Kidney Disease, and bilateral thigh wounds measuring about 28 x 11 cm and another wound in the abdomen. Till recently, the patient was in severe pain, faced mobility challenges and pressure ulcers at various areas of skin with inflammation. The infecting pathogen was a metallo- β -lactamase-harboring *Pseudomonas aeruginosa*, which is one of the toughest resistance mechanisms known. After 2 weeks of Zaynich (Zidebactam/Cefepime- WCK 5222) treatment, the thigh wound beds started looking healthy with diminished bacterial load and xenograft placement could be undertaken. Eventually, the abdominal wound completely healed and bilateral thigh wounds fully incorporated the graft. After 4 weeks of Zaynich treatment, since the wounds appeared healed, no cultures were taken. Zaynich (Zidebactam/Cefepime- WCK 5222) was well-tolerated by the patient during the 4-weeks treatment.

Zaynich (Zidebactam/Cefepime- WCK 5222) is currently undergoing a multi-national Phase 3 study which is expected to support its registration/marketing authorization globally. Earlier, several Phase 1 studies including clinical pharmacology studies with Zaynich (Zidebactam/Cefepime- WCK 5222) were conducted in US.

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.