PRESS RELEASE

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Globally renowned US body Clinical and Laboratory Standards Institute (CLSI) awards high susceptibility breakpoints to Zaynich (Zidebactam/Cefepime- WCK 5222)

In the June 24, 2024 plenary session of Clinical and Laboratory Standards Institute (CLSI), Zaynich (Zidebactam/Cefepime- WCK 5222) has been granted a susceptibility breakpoint of 64 mg/L for around 10 Gram negative pathogens showing high resistance rates. Susceptibility breakpoints guides the doctors about selection of most efficacious antibiotic for treating various infections caused by different pathogens.

A high breakpoint of 64 mg/L suggests Zaynich's (Zidebactam/Cefepime- WCK 5222) strong potential to cover all the clinically important, extreme drug resistant Gram negative pathogens in seriously ill patients. Since the introduction of penicillin in 1928, more than 250 antibiotics have been approved and used clinically, however, this is 1st time ever that an antibiotic has been granted a susceptible breakpoint of as high as 64 mg/L for all the three families of Gram negative pathogens; Enterobacterales, Pseudomonas and Acinetobacter. Pending Zaynich's (Zidebactam/Cefepime- WCK 5222) formal approval, CLSI has designated these breakpoints as Investigational Breakpoints to facilitate clinical trials and compassionate use of this life saving antibiotic.

In granting of the breakpoints, >8 years of research data on Zaynich (Zidebactam/Cefepime- WCK 5222) was reviewed by three sub-committees of CLSI sequentially, followed by independent rounds of voting by the members at each stage. The final plenary session unanimously approved the investigational breakpoints for Zaynich (Zidebactam/Cefepime- WCK 5222).

During >1 year, Zaynich (Zidebactam/Cefepime- WCK 5222), has been successfully used to treat 30 patients under compassionate use who were inflicted with infections caused by extreme-drug resistant Gram-negative pathogens, including Pseudomonas, Klebsiella, E. coli, Acinetobacter, and Serratia not amenable to any of the available antibiotics. The high breakpoints assigned to Zaynich are supportive of consistent clinical cure and microbiological eradication demonstrated in these compassionate use patients.

Currently, Zaynich (Zidebactam/Cefepime- WCK 5222) is undergoing a multinational Phase 3 study, which is expected to be completed by FY 2025, facilitating its global registration and marketing authorization.

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.