PRESS RELEASE

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Wockhardt's another breakthrough antibiotic: once-a-day β-lactam enhancer, WCK 6777 with unique out-patient treatment advantage granted Fast Track designation by US FDA and successfully completes Phase I study conducted by National Institutes of Health, US

Wockhardt is advancing the development of several new antibiotics aimed at combating difficult-to-treat drug-resistant bacterial infections that drive anti-microbial resistance (AMR) linked mortality and morbidity. Recently, one of its unique once-a-day, β-lactam enhancer based MDR-active antibiotic, WCK 6777 (Ertapenem/Zidebactam) has successfully completed a Phase I study conducted by the Division of Microbiology and Infectious Diseases (DMID) at the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) in US. Recognizing the therapeutic potential of WCK 6777 for infections caused by MDR Gram negative pathogens, DMID of NIH had selected this drug for Phase I studies. Zidebactam has already demonstrated promising safety profile in Phase I and on-going Phase II & III studies in combination with Cefepime (WCK 5222).

Additionally, recognizing its potential to meet significant unmet medical needs, the US FDA has recently granted Fast Track designation to WCK 6777 for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, and complicated intra-abdominal infections (cIAI).

WCK 6777 is the only once-a-day drug in global antibiotic pipeline designed for outpatient-parenteral antimicrobial therapy (OPAT) in ambulatory settings. WCK 6777 is active against entire range of meropenem-resistant Gram negative pathogens generally encountered in community as well as hospital urinary tract infections (UTI) and intra-abdominal infections (IAI). Such a therapeutic option is expected to cut hospital admissions, facilitate early patient discharge and thus offer patient-centred care for MDR infections.

Phase I study of WCK 6777 involved 52 participants and was designed as a double-blind, placebo-controlled, multiple-ascending dose trial in healthy volunteers. The trial rigorously assessed the safety and pharmacokinetics of WCK 6777, administering intravenous doses higher than the anticipated clinical dose over a period of 7 days. Results demonstrated a promising safety profile, with WCK 6777 (up to 3 grams + 3 grams daily) being well-tolerated, and no serious or unexpected adverse events reported. None

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of the subjects withdrew or were discontinued from the study due to treatment-related adverse events.

Pharmacokinetic analysis revealed consistent exposure levels of both ertapenem and zidebactam, with no significant interactions when co-administered daily for the duration of the study.

The promising safety data from this study paves the way for the advancement of WCK 6777 into Phase II / III clinical trials.

Globally, incidence of UTI were 404.61 million with 236,790 deaths estimated in 2019. It is estimated that 1 in 100 of US adults will experience a cUTI each year, resulting in approximately 2.8 million cUTI cases and annualized total US costs in excess of $ 6 billion. There are 600,000 hospital admissions among adults for cUTIs each year in the United States with each episode costing an average of $ 9,441.

Emerging therapeutic role of WCK 6777 makes it uniquely positioned to cater to the vast unmet need in the management of infections outside the hospital.

About Ertapenem/Zidebactam (WCK 6777)
Through independent studies, WCK 6777 is shown to be active against several carbapenem-resistant Gram-negative pathogens such as E. coli and Klebsiella including those producing metallo β-lactamases, often encountered in community as well as hospital infections such as urinary tract infections (UTI). Other recently approved antibiotics do not address this issue. Owing to its activity against CDC/WHO/FDA categorized priority pathogens, WCK 6777 was granted a qualified infectious disease product (QIDP) designation in 2020 by U.S. FDA.

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. Wockhardt's flagship novel mechanism based antibiotic, Zaynich (Cepefime/Zidebactam), designed to target extreme-drug resistant Gram negative infections, is undergoing a global Phase 3 study. Zaynich has already saved lives of >35 critically ill patients under compassionate use over last one year and is also being evaluated in a clinical study involving patients with documented meropenem-resistant infections. Clinical and Laboratory Standards Institute (CLSI), US has granted it a susceptibility breakpoint of 64 mg/L for 10 Gram negative pathogens showing high resistance rates, signifying strong potential to cover all the clinically important, extreme drug resistant Gram negative pathogens in seriously ill patients.