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WOCKHARDT RECEIVES ACKNOWLEDGEMENT OF ITS BREAKTHROUGH SUPERDRUG ANTIBIOTIC WCK 5222 FOR PHASE III CLINICAL TRIAL FROM US FDA

In a recent meeting between Wockhardt Research team and US FDA New Drug Antibiotic Regulatory team, US FDA agreed to abridged clinical trial for Phase III for Wockhardt's superdrug antibiotic WCK 5222. This was based on the evaluation by US FDA of its preclinical and clinical data of Phase I establishing safety and clinical scope of efficacy for the drug. WCK 5222 contains Zidebactam coming out of Wockhardt's Drug Discovery team of 140 strong scientists working for antibiotic research since last 20 years.

WCK 5222 is a combination of Zidebactam and Cefepime. This superdrug introduces an entire new class of antibiotic treatment. Earlier US FDA has granted a breakthrough fast track clinical trial and approval process (QIDP status) for this superdrug. This drug meets the urgent threat of Carbapenem-resistant Enterobacteriaceae and serious threats like Multidrug-resistant Acinetobacter, Extended spectrum β -lactamase producing Enterobacteriaceae (ESBLs), Drug-resistant Salmonella typhi and Multidrug-resistant Pseudomonas aeruginosa. This is the categorisation based on which US FDA has given this special QIDP status. Wockhardt has taken this antibiotic for a worldwide clinical development. This drug in scientific community is well documented by a large number of oral and scientific poster presentation at ASM Microbe at Boston and ECCMID at Amsterdam and ID week at New Orleans.

One of the constituents of WCK 5222 is Zidebactam, which is an antibiotic with a novel β -lactam enhancer mechanism that facilitates overcoming of multiple resistance mechanisms in Gram negative superbugs, including the most dreaded mechanism called New Delhi metallo β -lactamase (NDM) which renders the last line of antibiotics (carbapenems) ineffective. WCK 5222 is also active against the recently reported colistin-resistant strains of Gram negative pathogens.

Thus, WCK 5222 is expected to be a life-saving destination therapy for serious hospital-acquired infections such as pneumonia, ventilator associated pneumonia, blood stream infections.

Citing Lord Jim O'Neill report on 'The Review on Antimicrobial Resistance', currently more than 700,000 deaths are attributable to antimicrobial resistance every year and it is estimated that by year 2050, if no effective drugs are developed for these superbugs, 10 million lives a year and cumulative US\$ 100 trillion of economic output are at risk due to the rise of drug-resistant infections.

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Wockhardt believes on successful clinical outcome of superdrug WCK 5222, millions of lives will be saved and hope that Lord Jim O'Neill's report prediction may not come true. The world is grappling with the problem of bacterial drug-resistance against currently known antibacterial. There is an active proposal in G20 to support antibiotic research. G20 views that lack of antibiotics indicates that antibiotic research is not commercially viable. This can be seen from the fact that from the period 1983 to 1992 there were 30 antibiotics launched and approved in regulated developed countries. However, since 2008 to 2016, there are only 7 drugs approved. India constitutes roughly 15% of the usage of antibiotics in the world. Based on successful launch of antibiotics they recommend giving outright grant of incentives to pharmaceutical industry.

Over last 20 years, Wockhardt synthesised over 6000 chemical molecules and now has five drugs which has entered phase II and phase III clinical trials. All these drugs have been given by US FDA a breakthrough status i.e QIDP. Three of these drugs are for gram positive organism and two of these drugs are for gram negative organism.

Over last 10 years global patents filed for antibacterial have declined by 60%, whereas patents filed by Wockhardt in these 10 years has increased by 315%.

There are 10 other companies who are involved in antibiotic research and collectively have 11 drugs in the pipeline at clinical stage. However, Wockhardt alone has five drugs.

Wockhardt expects global clinical launch of WCK 5222 during the year 2020-21.

Antimicrobial resistance (AMR) occurs when micro-organisms (as bacteria, viruses, fungi and parasites) change in ways that render the medications used to cure the infections they cause, ineffective. When the microorganisms become resistant to most antimicrobials they are often referred to as "superbugs". These resistant infections are usually associated with higher rate of mortality, extended hospitalization, can spread to others, and impose huge costs to individuals and society.

AMR is of particular concern in developing countries like India, as the burden of infectious disease is high and the healthcare spending is low. Today, India has one of the highest bacterial disease burden and the second highest antibiotics consumption in the world. Therefore, to overcome the morbidity and mortality due to these infections, novel antibiotics effective against superbugs have a critical role.

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In recently concluded 7 year surveillance study in India sponsored by Bill and Melinda Gates Foundation covering major hospitals and community pantogens from 696 sectors of India have concluded that antibiotic resistance are significant against antibiotic in many cases of Klebsiella, Pseudomonas, Acinetobacter, E.Coli and S.aureus (MRSA) and it ranges 47% to 80%. These are life threatening organism. This is where WCK 5222 and other antibiotics in Wockhardt Drug Discovery programme will help to control the menace of superbug resistance.

20 years of research and deep involvement of 104 scientists have made it possible for us to develop an entirely new class of antibiotic i.e β -lactam Enhancer. This is a normal structure which provides extra ordinary killing power for superbugs.

We recognised that antibiotic research was on decline 20 years ago and we devoted our efforts to find new antibiotics as we were sure that the superbugs will develop resistance. Today more than 700000 lives are lost every year because of these superbugs and lack of antibiotics. Wockhardt's break through drug, Zidebactam is the answer for these superbugs.

About Wockhardt :

Wockhardt is a Global Pharmaceutical and Biotech company employing over 10,000 people and 27 nationalities with presence in USA, UK, Ireland, 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 62% of its global revenues coming from international businesses. Wockhardt is home to 850 scientists, of whom 100 are doctorates. Wockhardt is the only company in the world where USFDA has given QIDP Status (Qualified Infectious Diseases Programme) for 5 of our Anti-bacterial discovery programmes – 2 of them are Gram Negative and 3 Gram Positive. Wockhardt's entire Anti-infective portfolio particularly addresses the specific bacterial organism where resistances are high and breakthrough antibiotics are needed.