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Wockhardt receives DCGI approval for new drug to tackle AMR

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The new drug will target superbug like Methicillin-resistant Staphylococcus aureus (MRSA), which is a leading cause of rising antimicrobial resistance (AMR)

Indian drug regulator, DCGI has approved Wockhardt's 2 new antibiotics, EMROK (IV) and EMROK O (Oral), for acute bacterial skin and skin structure Infections including diabetic foot infections and concurrent bacteraemia based on the Phase 3

study involving 500 patients in 40 centres across India. The new drug will target superbug like Methicillin resistant Staphylococcus aureus (MRSA), which is a leading cause of rising antimicrobial resistance (AMR).

The size of Indian Antibiotic market is approx. 16,000 Crore, growing at 7% and is one of the largest therapeutic segment, with a 12% market share of the Indian Pharmaceutical Market.

“By virtue of its broad spectrum activity against widely prevalent pathogens including MRSA, superior safety over the currently available anti-MRSA agents and its unique properties, I believe EMROK/EMROK-O has a strong potential to effectively address the unmet medical need of the clinicians in the country thereby helping to reduce the morbidity and mortality”- said Dr. Habil Khorakiwala, Founder Chairman, Wockhardt Group.

Antimicrobial Resistance: A Medical Challenge (38% Resistance in India)

AMR is a major public health problem globally. India carries one of the largest burdens of drugâ??resistant pathogens worldwide. Infections caused by drug-resistant organisms could lead to increased mortality and prolonged duration of hospitalization, causing a huge financial burden to the affected persons, health-care systems, and hinder the goals of sustainable development. Two million deaths are projected to occur in India due to AMR by the year 2050. World Health Organisation (WHO) in 2017 has listed Methicillin resistant S. aureus (MRSA) as a ‘high’ priority pathogen due to high prevalence of resistance, mortality rate, burden on community and health care settings. In 2018, a national study conducted by the Indian council of Medical research (ICMR) and Anti-microbial resistant surveillance network (AMRSN) group highlighted the high prevalence of 38.6% of MRSA in India4. A recent Indian study reports that 1 in 6 patients infected with multidrug resistant Gram positive infections die in intensive care units.

Limitations of Current Treatments

Currently available anti-MRSA agents have multiple side effects such as kidney damage, decrease in platelet cell counts, muscle pain, to name a few; which limits their use for a longer period and compromise the safety of critically ill patients in the ICU. The patient management is further complicated due to increasing resistance to these agents and drying antimicrobial pipeline.

EMROK / EMROK O: The Modern Gram positive Antibiotic against Methicillin Resistant Staphylococcus aureus Infections

EMROK and EMROK-O are the first novel chemical entity antibiotics researched and developed in India with various international collaborations across globe. While the non-clinical and Phase 1 studies have been undertaken in U.S. Europe and India, the Phase 2 and Phase 3 clinical studies have been successfully completed in India.

More than 50 international publications/posters in top-notch journals/scientific conferences and studies by leading international experts have established that EMROK/EMROK-O represents a truly multi-spectrum MRSA drug with potent bactericidal action against Gram positive, quinolone susceptible Gram negative, anaerobic and atypical bacteria.

Clinical and non-clinical studies have established advantageous safety features of EMROK/EMROK-O compared to older MRSA drugs vancomycin, teicoplanin, daptomycin and linezolid which are beset with unfavourable features of nephrotoxicity, bone-marrow toxicity and muscle toxicity therefore cannot be given in patients with impaired kidney/liver function and seriously ill patients requiring for longer duration therapy.

After a significant gap of 14 years, a new anti-MRSA agent will be made available by Wockhardt as ‘EMROK’ for the management of resistant superbug.