

16<sup>th</sup> January, 2020

<b>National Stock Exchange of India Limited</b> Exchange Plaza Bandra Kurla Complex, Bandra (East), <b>Mumbai – 400 051</b>  <b><u>NSE Symbol – WOCKPHARMA</u></b>	<b>BSE Limited</b> Corporate Relations Department P J Towers, Dalal Street, <b>Mumbai – 400 001</b>  <b><u>Scrip Code – 532300</u></b>
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Dear Sir/ Madam,

**Sub: Press Release**

Please find enclosed herewith proposed Press Release titled "India's First New Discovery Antibiotics from Wockhardt Granted Indian Regulatory Approval."

Kindly take the above information on record.

**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 Diseases Programme) for 5 of our Anti-bacterial discovery programmes - 2 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 over 7000 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 72% of its global revenues coming from international businesses.

Thanking you,

For **Wockhardt Limited**



**Narendra Singh**  
**Company Secretary**

Encl: As above





## India's First New Discovery Antibiotics from Wockhardt Granted Indian Regulatory Approval

Mumbai, January 16, 2020

### Wockhardt: 1<sup>st</sup> Indian Company to Achieve Approval for New Discovered Antibiotics

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<sup>1</sup>.

"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 drug-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<sup>2</sup>.

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<sup>3</sup>. 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 India<sup>4</sup>. A recent Indian study reports that 1 in 6 patients infected with multidrug resistant Gram positive infections die in intensive care units<sup>5</sup>.

### 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<sup>6</sup>; 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®



## **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.

### **Wockhardt's research commitment to global antibiotic discovery**

Due to the combination of complexity of resistance mechanisms expressed by bacteria as well as lack of financial resources to fund antibiotic research, many major pharmaceutical firms have steered away from the antibiotic research in the last 30 years. In such challenging scenarios, Wockhardt Ltd. has invested for more than two decades in developing a strong antibiotic pipeline catering both multi drug resistant Gram positive and Gram negative pathogens and is the only company in the world having five antibiotics against superbugs in the late phase of clinical development. All these antibiotics, because of their promising activity against MDR pathogens, have received US FDA-QIDP status for expediting the drug development cycle. Out of the five, the first two antibiotics - EMROK and EMROK-O have been approved by DCGI recently and will be launched soon.

### **Bibliography:**

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# EMROK®

# EMROK O®