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

Wockhardt: 1st 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[1].

"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[2].

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[3]. 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[4]. A recent Indian study reports that 1 in 6 patients infected with multidrug resistant Gram positive infections die in intensive care units[5].

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[6]; 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.

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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.

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EMROK/EMROK O: List of International publication/Posters

International Publications

1. Levonadifloxacin (WCK 771) exerts potent intracellular activity against Staphylococcus aureus in THP-1 monocytes at clinically relevant concentrations. Jacques Dubois, Maïtée Dubois. Journal of Medical Microbiology, Nov 5 2019. DOI: 10.1099/jmm.0.001102. [Ahead of print]

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25. (F-534) Upadhyay DJ, et al., (41st ICAAC 2001, Chicago), WCK 771 A – An Investigational Anti-MRSA Fluoroquinolone (FQ) wit Potent Concentration Independent Cidal Action and An Unusual Ability to Kill Slow Growing Staphylococci.

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ANTIMICROBIAL RESISTANCE (AMR)

Rising concern globally as well as in India

Mortality

- 7 Lakh (current)
- 10 million (by 2050)

GDP

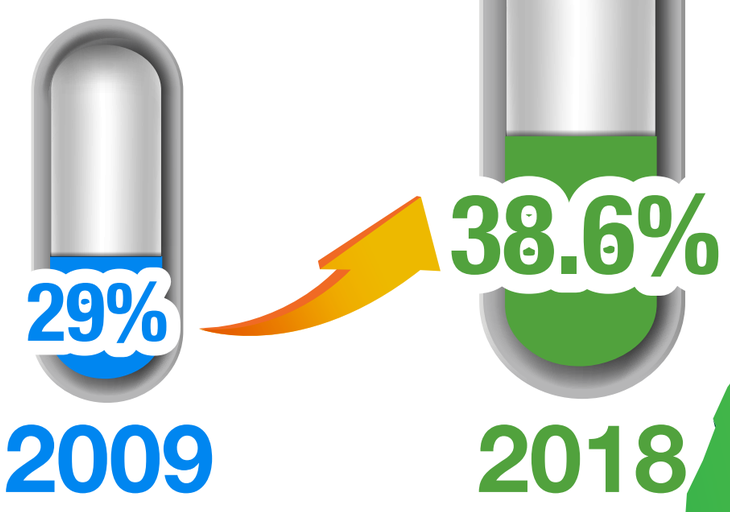
- ⬇ World's GDP 0.5% (current)
- ⬇ World's GDP 2-3.5% (by 2050)

India

- Mortality: 2 million (by 2050)

BURDEN OF MRSA IN INDIA

Prevalence



ICU Mortality

World Health Organization in 2017 listed MRSA as a **'high' priority** pathogen due to

- **Prevalence of resistance**
- **Mortality rate**
- **Burden on community**
- **Burden on health care settings**

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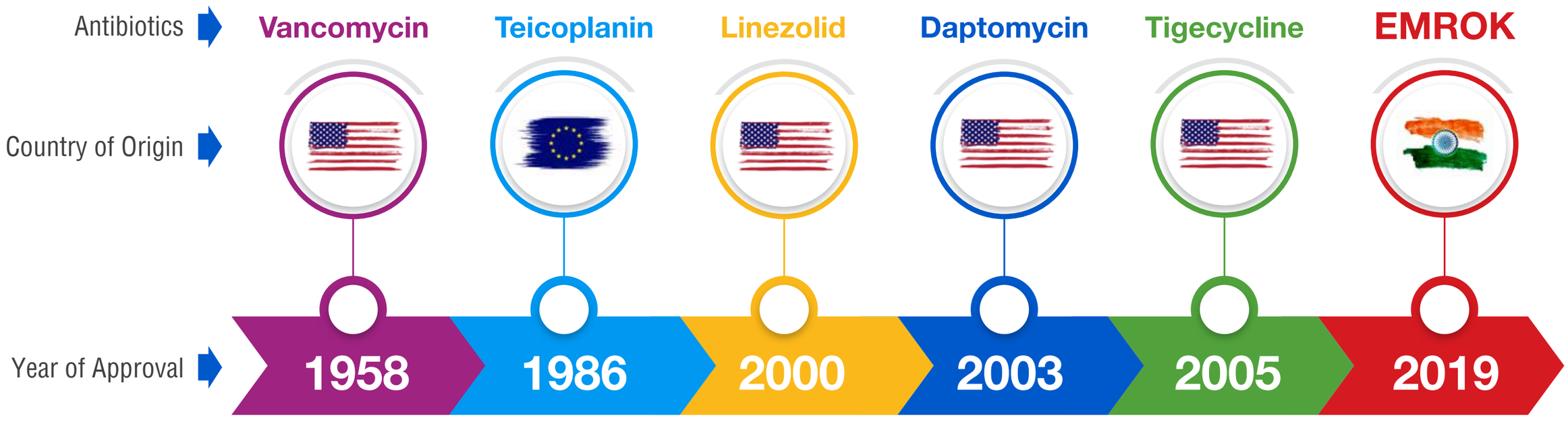
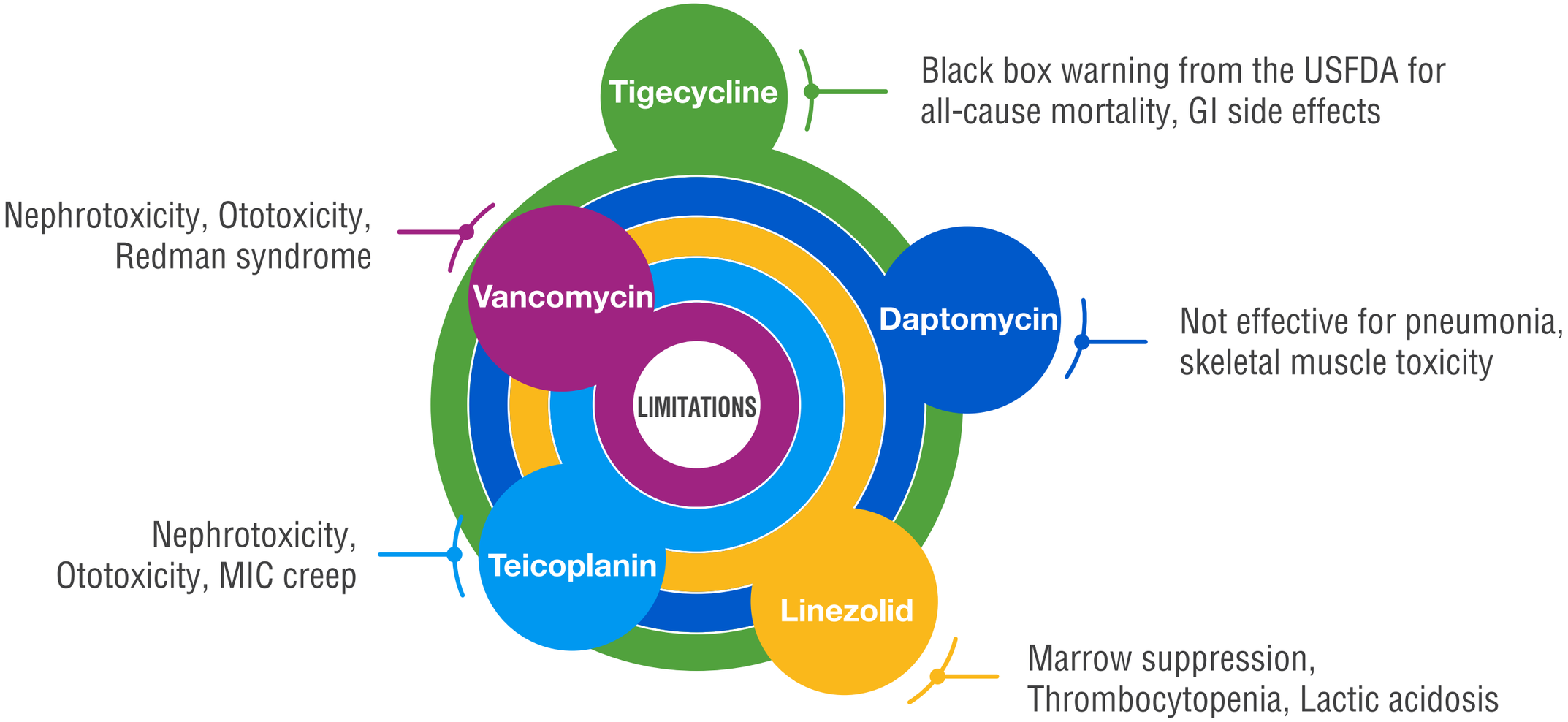
ANTI-MRSA AGENTS IN INDIA



LIMITATIONS OF CURRENTLY AVAILABLE ANTI-MRSA AGENTS



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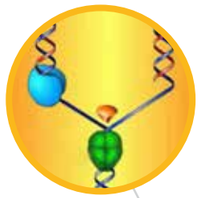
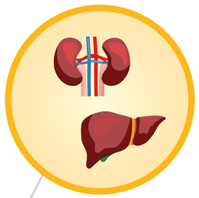
UNIQUE FEATURES OF EMROK

EMROK Unique Features

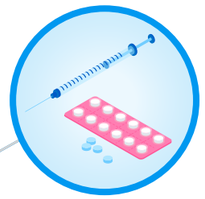
01 **Unique mechanism of action:**
Dual action on DNA gyrase & topo IV





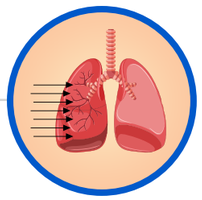
02 No dose adjustments in hepatic and renal impairment

03 Rapid bactericidal action



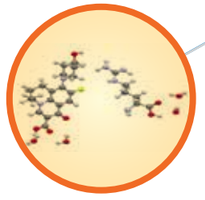
04 Easier to switch from IV to oral

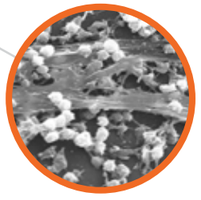
05 Suitable for Long term use



06 Better tissue penetration

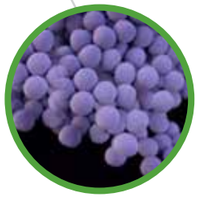
07 Unique structure





08 Eradicates biofilm

09 **Superior safety:**
NO } QT prolongation
Liver enzyme elevation
Phototoxic potential



10 **Unique Broad spectrum of coverage:**
Gram-positive including MRSA, Respiratory Gram negative, atypical and anaerobic bacteria

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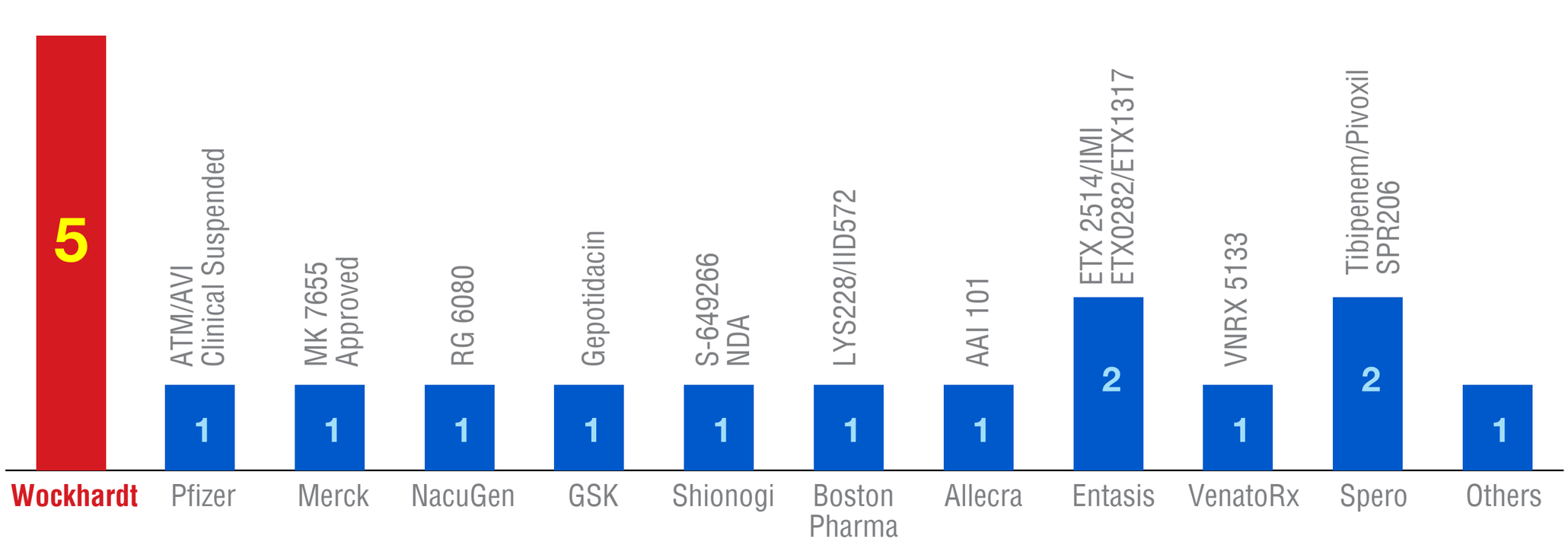
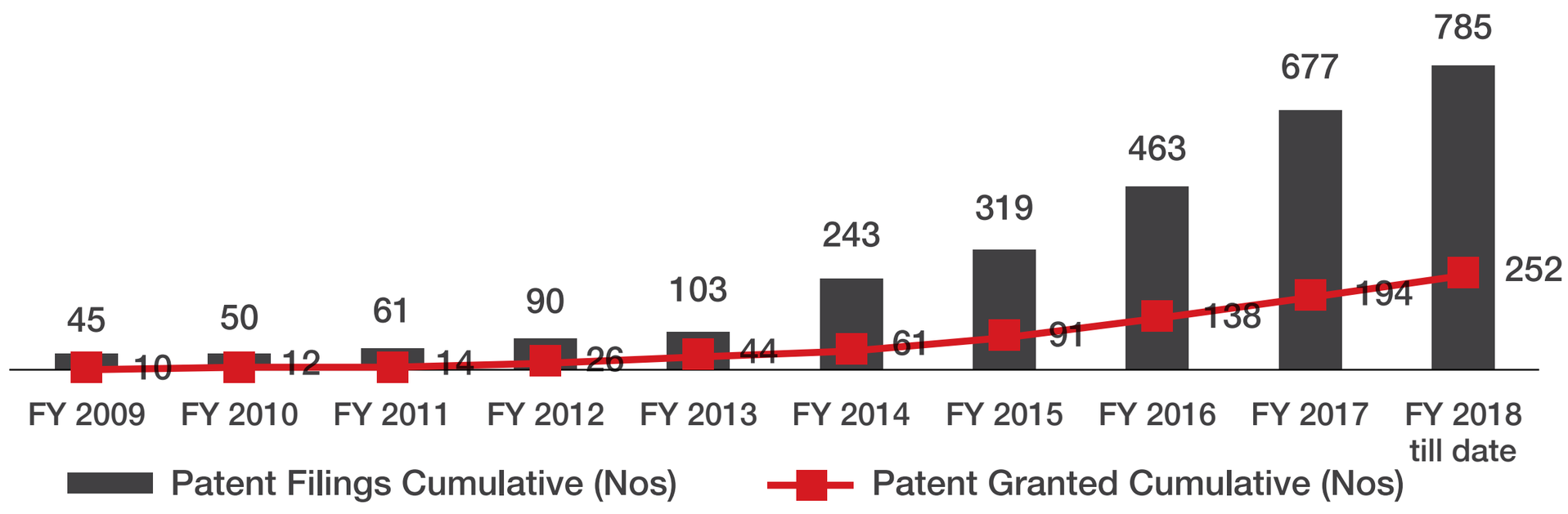
WOCKHARDT'S RESEARCH COMMITMENT TO GLOBAL ANTIBIOTIC DISCOVERY

Globally	**18 Superdrugs** in advanced clinical development with 12 companies
WOCKHARDT	**5 Superdrugs** in advanced clinical development

Highest QIDP status granted (5 NCEs) by US FDA to Wockhardt than any other company



Wockhardt has the Highest Patent filed in Antibiotic NCE



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