

Mumbai, 2nd January 2025

Indian Drug Regulator Approves Wockhardt's New Generation Oral Antibiotic Miqnaf[®] (Nafithromycin) for the Treatment of Community-Acquired Bacterial Pneumonia (CABP)

The Indian drug regulator, Central Drugs Standard Control Organization (CDSCO) has approved Miqnaf[®] (nafithromycin) as a new treatment for the Community-Acquired Bacterial Pneumonia (CABP) in Adults. Miqnaf[®] is an ultra-short course, once-a-day, 3-day treatment for CABP including those caused by multi-drug resistant (MDR) pathogens. The approval follows a favourable recommendation for manufacture and marketing of Nafithromycin from the Subject Expert Committee (SEC) of CDSCO.

Over >15 years, Miqnaf[®] underwent extensive non-clinical and clinical studies which include human trials in U.S, Europe, South Africa and India. It represents a new macrolide based treatment for CABP in India almost after a gap of 30 years. Moreover, the ultra-short course regimen enhances the patients' compliance to treatment resulting in favourable outcome. In India, antibiotic resistance is a burning issue including in community pneumonia cases. A key feature of Miqnaf[®] is its coverage of entire range of community respiratory pathogens including pneumococci resistant to azithromycin and amoxicillin/clavulanate, making it a promising monotherapy option for community-acquired bacterial pneumonia.

CABP affects millions of people worldwide with 23% of the global disease burden borne by India. CABP and other respiratory infections could be caused by several bacterial pathogens, the dominant being *S. pneumoniae* and *H. influenzae* and also by atypical respiratory pathogens such as *Mycoplasma*, *Chlamydia* and *Legionella*. The current oral antibiotics such as azithromycin face significant resistance challenges, while amoxicillin/clavulanate lack the coverage of atypicals, as a result, patients often require hospitalization to take intravenous treatment, which enhances the risk of hospital-acquired infections and imposes higher cost. Miqnaf[®] is designed to obviate the need of such hospitalization.

Wockhardt plans to launch Miqnaf[®] in the Indian market in coming few months.

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 antibiotics 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.

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 Disease Product) for 6 of our Anti-bacterial discovery programmes – 3 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 around ~2600 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 79% of its global revenues coming from international businesses.