Wockhardt Limited
Registered Office:
D-4, MIDC, Chikalthana
Chhatrapati Sambhajinagar
431006, India
Tel.: +91-22-2653 4444
CIN: L24230MH1999PLC120720
www.wockhardt.com

PRESS RELEASE

Mumbai, 11th October 2024

Wockhardt's yet another novel antibiotic Miqnaf™ (Nafithromycin) receives favourable recommendation from Subject Expert Committee of Central Drugs Standard Control Organization (CDSCO) for the Treatment for Community-Acquired Bacterial Pneumonia (CABP)

The Subject Expert Committee (SEC) of Indian drug regulator, Central Drugs Standard Control Organization (CDSCO) has provided a favourable recommendation for Wockhardt's novel antibiotic Miqnaf™ (nafithromycin) discovered and developed for the treatment of Community-Acquired Bacterial Pneumonia (CABP) in Adults. The SEC recommendation is based on CDSCO's comprehensive review of product dossier consisting of non-clinical, US/EU Phase 1, Global Phase 2 and India Phase 3 clinical studies conducted over last 15 years. A positive opinion from SEC of CDSCO would pave the way for gaining DCGI's final approval for Miqnaf™.

Miqnaf™ is globally, 1st-ever, Once-a-Day (OD) 3-days-only treatment for CABP patients including those caused by multi-drug resistant (MDR) bugs. The attractive feature of Miqnaf™ is that it is highly active against azithromycin and amoxicillin/clavulanate resistant Pneumococci, as well as entire range of pathogens involved in such infections and thus offering a monotherapy option. Earlier, a lung penetration study conducted in the US demonstrated best-in-class lung concentrations of Miqnaf™ enabling to evolve a convenient, compliance-friendly treatment for respiratory infections. Miqnaf™ is expected to play a significant role in offering a reliable treatment option in the community and thus would obviate the need of hospitalization.

Community-acquired pneumonia is the most common infection leading to hospitalization and deaths. Children and older adults are particularly vulnerable. Globally, 2.4 million annual deaths are caused by lower respiratory tract infections. India contributes to 23% of global community pneumonia burden.

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 medicines 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.