

PRESS RELEASEMumbai, 11th December, 2023**Wockhardt announces successful completion of pivotal Phase 3 pneumonia study of its macrolide antibiotic Nafithromycin WCK 4873**

Wockhardt is pleased to announce the completion of the pivotal Phase 3 pneumonia Study of its macrolide antibiotic Nafithromycin WCK 4873.

Wockhardt NCE, WCK 4873 named as Nafithromycin was comparatively evaluated in multi-centre double blind Phase 3 pneumonia study employing the last-line respiratory antibiotic Moxifloxacin. The results of the study showed that an ultrashort course of three-day treatment with Nafithromycin is as effective as seven-day therapy with Moxifloxacin. The findings of Phase 3 study are in line with Phase 2 study conducted in the US and Europe. A human lung penetration study conducted in the US revealed that Nafithromycin possesses a remarkable feature of sustained high lung concentration built-up over five days following just three days of dosing. Human Lung exposure of Nafithromycin is 8 times higher than Azithromycin and potency being 10-100 times higher for certain respiratory pathogens.

In Phase 3 study, three-day treatment with Nafithromycin resulted in clinical cure for 96.7% of patients as against clinical cure rate of 94.5 % in Moxifloxacin arm. The Phase 3 study outcome establishes broad-spectrum efficacy of Nafithromycin against Gram-positive respiratory pathogens, fastidious Gram-negative pathogens as well as therapeutically challenging intracellular atypical pathogens such as *Mycoplasma pneumoniae*, which were recently implicated for the surge of hospitalisations in China due to pneumonia. A significant proportion of study patients were infected with pathogens showing resistance to Azithromycin, Amoxicillin+clavulanic acid and Levofloxacin. The role of Nafithromycin in managing such patients would be of heightened interest to clinicians.

The Phase 3 study did not encounter any serious Adverse Event (AE), all the reported AEs were mild, and most were considered unrelated to the study drugs by the investigators except for nausea and gastrointestinal effects.

Importantly, the study also establishes that Nafithromycin represents a first ever macrolide in 30 years which has successfully completed clinical development for the indication of community acquired bacterial pneumonia. The currently available macrolide antibiotics Azithromycin and Clarithromycin were approved in 1988 and 1991 respectively. Since then no new macrolide antibiotics have been approved despite pneumonia causing about 2.5 million deaths annually worldwide as per WHO.

Recent ICMR surveillance data shows 65% resistance to Erythromycin in Indian pneumococcal isolates and globally up to 40% resists to Azithromycin. China has alarmingly high incidence of over 80% resistance to azithromycin among pneumococci.

As per the infectious disease related mortality burden reported in the December 2022 issue of the Lancet, estimated deaths in India due to pneumococcal infection amounted to 151,768. In conclusion, Nafithromycin is a major advancement in 30 years for treatment of pneumonia, which is effective and safe for community usage for resistant organisms.

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WINS****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.
