

Press Release – 21.05.2015

## **Wockhardt receives Qualified Infectious Disease Product (QIDP) designation for its new Drug WCK 4873 from U.S. FDA**

Wockhardt Limited announced today that that US Food and Drug Administration (FDA) has granted WCK 4873, a product from their New Drug Discovery program, Qualified Infectious Disease Product (QIDP) status. This is the third product from Wockhardt to receive this coveted status after WCK 771 and WCK 2349 last year and provides a strong boost to its drug development program.

Dr. Habil Khorakiwala, Wockhardt's Chairman said: "We are pleased that WCK 4873 has received the QIDP status, third for the company. WCK 4873 is a new class of antibiotic drug which will be used for the treatment of Community Acquired Bacterial Pneumonia (CABP) which has risen by alarming proportions globally"

Dr Khorakiwala further added : "There is a global crisis of availability of antibiotics to fight resistant bacteria. Indian regulator also needs to recognise this crisis and evolve new regulatory pathway for faster clinical trials and approval on the lines of the US FDA. In fact crisis in India for bacterial drug resistant is significantly high and we are losing lives every day. In US and Europe there are more than 50000 deaths every year because of these resistant pathogens. Early identification of antibiotic crisis by Wockhardt has resulted in this unique achievement".

QIDP for WCK 4873 is significant achievement in line with same received earlier for WCK 771 and WCK 2349 which are effective in treatment of Hospital Acquired Bacterial Pneumonia (HABP) and Skin & Skin Structure Infections (SSSI) caused by a class of pathogens called MRSA (Methicillin-resistant Staphylococcus Aureus). WCK 4873 will be entering its Phase 2 global clinical trials later this year.

QIDP status is granted to drugs, identified by CDC (Centre for Disease Control, USA), that act against pathogens which have a high degree of unmet need in their treatment. QIDP status provides fast track clinical development and review of the drug application by US FDA for drug approval and a five-year extension of market exclusivity post product approval in the USA. QIDP was constituted under Generating Antibiotic Incentives Now (GAIN) Act in 2012 as part of the FDA Safety and Innovation Act to underline the urgency in new antibiotics development.

### **About Wockhardt :**

Wockhardt is a Research based and technology intensive global pharmaceutical and biotechnology company. It's multi-disciplinary and innovative R&D programmes globally, are strongly focused on creating Intellectual Properties. It has 3 research centres globally and manufacturing facilities across India, USA, UK and Ireland. Wockhardt has a significant presence in USA, Europe and India, with 79% of its global revenues coming from international businesses. With a large pool of Patents and Intellectual Property knowhow, Wockhardt is home to 850 scientists, of whom 80 are doctorates. In all, Wockhardt has 300 Patents granted worldwide. In biotechnology research, it has built competent 'Concept to Market' capability in all facets of development and manufacture of recombinant biopharmaceuticals. Wockhardt boasts of a multi-ethnic workforce of more than 8,600 people from 21 different nationalities.