

Press Release

US FDA grants breakthrough (QIDP) drug discovery status to the New Antibiotic of Wockhardt

Mumbai, 8th December, 2015

Wockhardt Limited announced today that US Food and Drug Administration (FDA) has granted WCK 5222, a product from their breakthrough New Drug Discovery program in Anti Infectives, Qualified Infectious Disease Product (QIDP) status. This is the fourth product from Wockhardt to receive this coveted status. During last year, Wockhardt received approval for WCK 771 & WCK 2349 and in early this year approval was received for WCK 4873. The only company globally to receive QIDP status for 4 drugs from US FDA.

Dr. Habil Khorakiwala, Wockhardt's Chairman said: "We are pleased that WCK 5222 has received the coveted QIDP status, fourth for the Company in quick succession. WCK 5222 is a new class of antibiotic for gram negative terrain for complicated Urinary Tract Infections and Hospital Acquired Bacterial Pneumonia (HABP)/VABP. We believe that when WCK 5222 is approved will save many lives worldwide".

Dr. Khorakiwala further added that there is a global crisis of availability of antibiotics to fight resistant bacteria and there has been a big void in Anti Infective as relatively very few drugs have been discovered in the last decade.

He also added that the Company's relentless focus for almost two decades in the Anti Infective space has started showing recognition with consecutive approvals for QIDP in quick succession. With the rise in number of new organisms and new strains of old organisms with significant resistance for existing medicines, the Company with its array of under development drugs in this space aims to counter these unmet needs in both gram positive and gram negative bacterial infections in both regulated and unregulated markets.

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.

Dr. Khorakiwala commented that such overhanging crisis needs to be recognised with evolving new regulatory pathway for faster clinical trials and approvals. In fact the crisis in India for bacterial drug resistant is significantly high and human lives are lost every day. Early identification of antibiotic crisis by Wockhardt has resulted in this unique achievement. Wockhardt, as on date, are one of those unique R&D focussed organisation to have four such coveted status in its breakthrough New Drug Discovery Program.

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 411 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 from 21 different nationalities.