

# Wockhardt's drug discovery gets a boost with fast track approval by USFDA

**WCK 771 and WCK 2349, the two anti infective drugs from Wockhardt, get QIDP status**

- Wockhardt becomes the first Indian pharma company to achieve this mark
- QIDP status allows for fast track review of the drug application by US FDA paving way for an early launch
- Also grants a 5 year extension to the drug patents in USA

**Mumbai, August 31, 2014: (BSE code: 532300)** Wockhardt Ltd's New Drug Discovery program in Anti-Infective research received a major boost after two of its drugs, WCK 771 and WCK 2349, received the coveted Qualified Infectious Disease Product (QIDP) status from the US FDA. This is the first instance of an Indian Pharmaceutical company receiving a QIDP status.

A QIDP status is granted to drugs which act against pathogens which have a high degree of unmet need in their treatment and are identified by the Centre for Disease Control, USA – a top US government health and safety body. QIDP status allows for fast track review of the drug application by US FDA paving way for an early launch.

Globally, there is a significant antibiotic vacuum due to dual impact of rise in new resistant pathogens and declining research in this area. Over the years, Wockhardt has developed a strong anti-infective program which focuses on development of drugs which target this antibiotic gap. Both WCK 771 and WCK 2349 act against one of the globally rising class of pathogens, MRSA (Methicillin-resistant Staphylococcus Aureus) which causes a range of diseases from the skin infection to severe respiratory infections. In case of severe infections like Hospital Acquired Pneumonia (HAP), current medical cure has a very limited reach causing a high unmet need and mortality. Both of these drugs are effective against MRSA and have shown potential in treatment of HAP.

Commenting on the achievement, Dr. Habil Khorakiwala, Founder Chairman and Group CEO, Wockhardt Ltd, said, "This is indeed a proud moment for us. Not only does the status allow for fast track review of our drug application, it also grants a 5 year extension to the drug patents in USA which is a major support for the commercial aspect of the drug. These drugs will be entering in their global Phase -3 clinical trials early next year."

WCK 771 is an intravenous (IV) drug while WCK 2349 is a solid oral tablet, which is a significant positive for the drug development scenario as currently there is very little advance drug research in developing solid oral dosages. Most of the research is in developing intravenous drugs.

Wockhardt started its Anti-infective program 17 years back in 1997 with single-minded focus on developing next generation antibiotics. Its new drug research pipeline targets some of the major infectious diseases which have limited cure available and has shown encouraging results for the same. Over the years it has significantly strengthened its new drug discovery base and created strong clinical studies and regulatory team and infrastructure.

## **About Wockhardt Ltd**

Wockhardt is a global pharmaceutical and biotechnology organisation, providing affordable, high-quality medicines for a healthier world. It is India's leading research-based global healthcare enterprise with relevance in the fields of Pharmaceuticals, Biotechnology and a chain of advanced Super Speciality Hospitals.

Wockhardt has 3 research centres and 12 manufacturing plants, with businesses ranging from the manufacture and marketing of Pharmaceutical and Bio-pharmaceutical formulations, Active Pharmaceutical Ingredients (APIs) and Vaccine.

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