

20th April, 2020

BSE Limited Corporate Relations Department P J Towers, Dalal Street Mumbai - 400 001 <u>Scrip Code: 532300</u>	National Stock Exchange of India Limited Listing Department Exchange Plaza Bandra Kurla Complex, Bandra (E), Mumbai - 400 051 <u>NSE Symbol – WOCKPHARMA</u>
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Dear Sir/ Madam,

Sub: Press Release

Please find enclosed herewith proposed Press Release titled “Wockhardt receives US FDA Qualified Infectious Disease Product designation for WCK 6777, a first ever once-a-day β -lactam enhancer class antibiotic.”

Kindly take the above information on record.

Thanking you,

For **Wockhardt Limited**



Narendra Singh
Company Secretary

Encl: As above



Wockhardt receives US FDA Qualified Infectious Disease Product designation for WCK 6777, a first ever once-a-day β -lactam enhancer class antibiotic

Mumbai, April 20, 2020

Pharmaceutical and biotechnology major Wockhardt has received the Qualified Infectious Disease Product ('QIDP') designation for WCK 6777 from the United States Food and Drug Administration ('USFDA'). WCK 6777 is a once-a-day combination antibiotic based on Wockhardt's NCE Zidebactam, which imparts WCK 6777 novel mechanism of β -lactam enhancer. Driven by the enhancer action, WCK 6777 overcomes an array of problematic bacterial resistance mechanisms such as metallo- β -lactamases, KPC and OXA carbapenemases. Further, Zidebactam has the unique ability to overpower other tough resistance mechanisms such as reduced drug uptake and drug efflux encountered in contemporary multidrug (MDR) resistant Gram negative pathogens. Being a once-a-day drug, WCK 6777 would be the first ever antibiotic facilitating the treatment of MDR infections in out-patient settings. Wockhardt's other Zidebactam-based product, WCK 5222, has received US FDA's nod for global Phase 3 clinical trial.

WCK 6777 for injection has been awarded QIDP for the following indications:

- Treatment of complicated urinary tract infections, including pyelonephritis (cUTI)
- Treatment of complicated intra-abdominal infections (cIAI)

"Wockhardt has planned for the global development of WCK 6777 covering important markets of the US, Europe, China and India", said Dr Habil Khorakiwala, Founder Chairman, Wockhardt Group.

The dual coveted objectives attained by this drug are the prevention of hospitalization and the

facilitation of early discharge of hospitalized patients.

The QIDP status is granted to drugs that are effective against a set of multidrug resistant pathogens identified by the CDC (Centre for Disease Control, USA), which have a high degree of unmet need in the treatment of patients infected by such pathogens. The status provides fast track clinical development and review of the drug application by US FDA for approval. The QIDP drug is also entitled for five-year extension of market exclusivity. 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 development of new antibiotics.

With WCK 6777 getting the QIDP status, Wockhardt has become the only company in the world to hold QIDP status for six antibiotics emerging from its anti-bacterial discovery programme. Three of these antibiotics target Gram Negative pathogens, and the other three are effective against Gram positive difficult-to-treat 'Superbugs'.

The other NCEs of Wockhardt that been conferred with the QIDP status by the US FDA are WCK 5222 and WCK 4282 (both targeting different Gram negative pathogens); WCK 4873 (once-a-day respiratory antibiotic active against MDR Pneumococci); and WCK 771 and WCK 2349 (broad spectrum anti - MRSA drugs). These NCEs are either in different stages of clinical development or have been approved. Earlier during the year, the Indian drug regulator DCGI had approved two new antibiotics developed by Wockhardt, EMROK (WCK 771 IV) and EMROK O (WCK 2349 Oral), for acute bacterial skin and skin

structure infections including diabetic foot infections and concurrent bacteraemia, based on the successful outcome of Phase 3 study involving 500 patients recruited in 40 centres across India.

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 employing over 7000 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 72% of its global revenues coming from international businesses.