Ref. No.: WOCK/SEC/SE/2024-25/085 31st January, 2025

BSE Limited Corporate Relations Department P J Towers Dalal Street Mumbai - 400 001 **Scrip Code: 532300**	**National Stock Exchange of India Limited** Exchange Plaza Bandra Kurla Complex Bandra (E) Mumbai - 400 051 **NSE Symbol: WOCKPHARMA**

Dear Sir/ Madam,

Subject: Submission pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ("Listing Regulations") - Press Release

Pursuant to Regulation 30 of Listing Regulations, please find enclosed Press Release –"Wockhardt's Zaynich® (Zidebactam/Cefepime, WCK 5222) achieves highest-ever efficacy meeting superiority in a global, pivotal, registration-enabling Phase III study in complicated urinary tract infection (cUTI) achieving 96.8% clinical cure rate".

A copy of the same will also be uploaded on the Company's website www.wockhardt.com

Kindly take the same on record please.

Thanking you,
For **Wockhardt Limited**

Rashmi Dinesh Mamtura
Digitally signed by Rashmi Dinesh Mamtura
Date: 2025.01.31 08:22:10 +05'30'

Rashmi Mamtura
Company Secretary

Encls: A/a

Wockhardt Limited
Registered Office:
D-4, MIDC, Chikalthana
Chhatrapati Sambhajinagar
431006, India
Tel.: +91-22-2653 4444
CIN: L24230MH1999PLC120720
www.wockhardt.com

PRESS RELEASE

Mumbai, 31st January 2025

Wockhardt's Zaynich® (Zidebactam/Cefepime, WCK 5222) achieves highest-ever efficacy meeting superiority in a global, pivotal, registration-enabling Phase III study in complicated urinary tract infection (cUTI) achieving 96.8% clinical cure rate

Zaynich® (Zidebactam/Cefepime, WCK 5222), Wockhardt's flagship discovery product has successfully completed a global, pivotal, registration-enabling Phase III study and demonstrated superiority compared with meropenem (89.0% vs 68.4%, respectively) in the US FDA & EMA (European Medicines Agency) primary efficacy endpoint defined as the combination of clinical cure and microbiologic eradication at test of cure (TOC, 7-10 days after last dose). With respect to clinical cure, Zaynich® achieved 96.8% efficacy. Such combined efficacy (achieving clinical cure and microbiologic cure) of Zaynich® is highest ever among all the FDA-approved novel antibiotics developed in last more than 10 years.

In a 1st for India, this milestone is a culmination of >14 years of end-to-end discovery and development of a novel Gram negative antibiotic by an Indian company to be marketed globally. In this blinded trial, Zaynich® was compared with gold standard, meropenem, in which Zaynich® met the DCGI-concurred and US FDA/EMA/pre-specified primary efficacy endpoint. Based on this study, Wockhardt intends to file new drug application (NDA) with US FDA and marketing authorization application (MAA) with EMA.

The Phase III study 'ENHANCE 1' enrolled 530 cUTI patients from US, Europe, LATAM, China and India spanning across 64 sites. Zaynich® showed clinical efficacy of 96.8% at test of cure (TOC, 7-10 days after last dose) while in the composite of clinical and microbiology cure (US FDA and EMA defined endpoints), Zaynich® showed superiority over meropenem (89.0% vs 68.4%, respectively) reflecting the impact of novel β-lactam enhancer mechanism of action. Zaynich® was well-tolerated and showed meropenem-comparable safety profile.

Gram-negative infections such as cUTI have become increasingly difficult to treat due to wide spread resistance to multiple classes of antibiotics. Zaynich® has the potential to treat a broad range of patients with cUTI due to multidrug-resistant (MDR) or extensively drug resistant (XDR) pathogens including Enterobacterales and Pseudomonas aeruginosa. In US and EU, > 8 Million cUTI cases are reported every year, reflecting the global burden of Gram negative infections.

Zaynich® has recently shown >97% clinical efficacy in a trial involving patients with confirmed meropenem-resistant infections spanning across hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), bloodstream infections (BSI), complicated intra-abdominal infections (cIAI), and cUTI. During past >2 years, under compassionate use, Zaynich® has been administered to 45 patients from India and US who were battling life-threating infections not responsive to any of the available antibiotics. Even before its formal approval, Zaynich® has

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drawn global attention as Wockhardt has been receiving request to supply the drug for compassionate use from countries such as US, UK, France, Australia, and Malaysia.

About Zaynich® (Zidebactam/Cefepime, WCK 5222)

Zaynich®, combination of Zidebactam & Cefepime, is Wockhardt's novel proprietary antibiotic, targeted towards multi-drug resistant Gram-negative infections. Zaynich® is a novel β-lactam enhancer mechanism of action drug, which overcomes all the clinically important resistance mechanisms in Gram negative pathogens including tough-to-treat Pseudomonas, Stenotrophomonas, Acinetobacter and Klebsiella. Such spectrum of activity of Zaynich® has been documented through >100 publications/presentations, majority from US and EU based independent experts/organizations. Zaynich® has completed multi-national Phase III study which would support its registration/marketing authorization globally. Earlier, several Phase I studies including clinical pharmacology studies with Zidebactam/Cefepime were conducted in US.

About Wockhardt's New Drug Discovery portfolio

Over the period of > 25 years, Wockhardt has focused its drug discovery efforts in the area of discovering novel medicines for multi-drug resistant infections. This has resulted in a portfolio of 6 products at various stages of clinical development and commercialization, each of which have been granted Qualified Infectious Disease Product status by the US FDA.

About Wockhardt

Wockhardt is a research based Global Pharmaceutical and Biotech company. Wockhardt is the only company having received QIDP Status (Qualified Infectious Disease Product) from US FDA for 6 of its 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.