Ref. No.: WOCK/SEC/SE/2025-26/050 1st December, 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 – "US FDA Accepts Wockhardt's New Drug Application for Breakthrough Antibiotic *Zaynich*".

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: 2025.12.01 11:31:51 +05'30'

Rashmi Mamtura
Company Secretary

Encls: A/a

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PRESS RELEASE

US FDA Accepts Wockhardt's New Drug Application for Breakthrough Antibiotic *Zaynich*

First-ever NDA Acceptance for an Indian Pharmaceutical Company Marks a Historic Milestone

Mumbai, India - December 1, 2025: Wockhardt Ltd. today announced that the United States Food and Drug Administration (US FDA) has formally accepted the New Drug Application (NDA) for its novel, first-in-class antibiotic **Zaynich**. The NDA was originally filed on **September 30, 2025**, and its acceptance marks a transformative moment—not only for Wockhardt, but also for the entire Indian pharmaceutical industry. This is **the first time in history that an NDA for a New Chemical Entity (NCE) from an Indian pharmaceutical company has been filed and accepted by the US FDA**.

Submitting an NDA to the US FDA represents one of the most stringent scientific and regulatory thresholds in global drug development. It demands robust clinical evidence, world-class manufacturing capabilities, and rigorous compliance across multidisciplinary domains. Wockhardt's achievement underscores the organization's scientific depth, innovation strength, and global-standard development excellence.

Zaynich has been granted **Fast Track designation** by the US FDA, recognizing its potential to address urgent and unmet medical needs. As part of this pathway, the FDA has committed to assign priority to Zaynich NDA review.

A novel β-lactam enhancer mechanism based Zaynich has garnered international attention for its potent activity against highly resistant Gram-negative pathogens—microbes responsible for prolonged hospitalizations and significant mortality worldwide. Its life-saving impact has already been demonstrated through compassionate use in critically ill patients in both India and the United States.

Over the past decade, Zaynich has become **one of the most extensively studied antibiotics globally**, reflecting a comprehensive, science-driven development program initiated by Wockhardt in **2011**. The company has successfully navigated a demanding non-clinical, clinical and regulatory pathway.

Commenting on the milestone, Wockhardt stated:
"The FDA's acceptance of the Zaynich NDA is a historic and proud moment for the organization and for India. It reaffirms our commitment to developing advanced anti-infective solutions for the world and demonstrates what Indian science and innovation can achieve on the global stage."

With Zaynich, Wockhardt continues to drive forward its mission of delivering path breaking anti-infective therapies that respond to some of the most serious threats in global healthcare.

About Wockhardt
Wockhardt is a global pharmaceutical and biotechnology company focused on developing innovative anti-infective solutions. With a legacy of scientific excellence and a mission to combat antimicrobial resistance, Wockhardt continues to pioneer next-generation therapies for a healthier world.

For media inquiries, please contact:
Corporate Communications, Wockhardt Ltd.