

**June 06, 2024**

National Stock Exchange of India Limited,  
Exchange Plaza, Bandra Kurla Complex,  
Bandra (E), Mumbai-400051

BSE Limited  
Phiroze Jeejeebhoy Towers, Dalal  
Street Fort, Mumbai- 400001

Symbol: **ORCHPHARMA**

Scrip Code: **524372**

**Subject: Press Release – Orchid Pharma Limited (“the Company”)**

Dear Sir/Madam,

In accordance to Regulation 30 read with Schedule III of Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015, as amended, kindly find enclosed the Press Release being released titled “**Orchid Pharma receives DCGI approval for its first invented and made-in-India Antibiotic Drug Combination of Cefepime and Enmetazobactam (NCE)**”

You are requested to take the above information on record.

Thanking You,

For **Orchid Pharma Limited**

**Kapil Dayya**  
**Company Secretary & Compliance Officer**

***Encl: As Above***

## **Orchid Pharma receives DCGI approval for its first invented and made-in-India Antibiotic Drug Combination of Cefepime and Enmetazobactam (NCE)**

This approval paves the way for launch of this advanced injectable therapy for patients in India

**New Delhi, 06 June 2024:** Orchid Pharma, based in Chennai, India, has received Drugs Controller General of India (DCGI) approval for the manufacturing and marketing of its invented New Chemical Entity Active Pharmaceutical Ingredient (API), Enmetazobactam.

DCGI has also granted permission to manufacture and market Finished Dosage Form (FDF) of **Cefepime and Enmetazobactam** as a dry powder injectable. This formulation is indicated for the treatment of complicated Urinary Tract Infections (cUTI) including acute Pyelonephritis, Hospital-Acquired Pneumonia (HAP) including Ventilator-associated pneumonia (VAP), and Bacteremia when it is associated or suspected to be associated with either complicated urinary tract infections or hospital-acquired pneumonia. With this approval, Orchid Pharma intends to improve the treatment landscape for serious infections in India, providing patients with access to advanced and effective therapy options.

Anti-Microbial resistance (AMR) is declared as the silent pandemic by UN and WHO and it has contributed to almost 5mn deaths in 2019. In addition to death and disability, AMR has significant economic costs. The World Bank estimates that AMR could result in US\$ 1 trillion additional healthcare costs by 2050, and US\$ 1 trillion to US\$ 3.4 trillion gross domestic product (GDP) losses per year by 2030. This new Combination Drug, provides a powerful treatment option against a range of severe infections caused by resistant bacteria, addressing a critical need in combating antimicrobial resistance.

Speaking on the approval, **Mr. Manish Dhanuka, Managing Director, Orchid Pharma**, said, “Enmetazobactam’s approval in India is personally fulfilling as being an Indian company, we wanted to expand access to advanced and affordable treatment options for patients in India. Orchid Pharma is committed to innovation and is poised to provide an effective solution for patients suffering from severe infections, particularly in the face of rising antimicrobial resistance. We continue our dedicated efforts towards research and development to address unmet medical needs.”

The company looks forward to the successful launch and distribution of Enmetazobactam and its combination with Cefepime for enhancing the treatment landscape for severe infections in India.

**About Orchid Pharma Limited:**

Established in 1992 as an export-oriented unit (EOU), Orchid Pharma Ltd. (Orchid) is a vertically integrated Company spanning the entire pharmaceutical value chain with established credentials in research, manufacturing, and marketing.

Orchid, is the only Indian Pharmaceutical Company, to ever have invented a New Chemical Entity (NCE, also colloquially called New Drug). The molecule is out licensed (on Royalty model) and now approved in US and Europe.

Orchid is a pioneer in Production of Quality Cephalosporins especially the Sterile Products, for which it is the one out of the only three USFDA approved facilities in the world, and the only one from India. Besides this, the facility has other approvals like EU GMP, ANVISA and PMDA.