February 23, 2024

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

Symbol: **ORCHPHARMA**

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

Scrip Code: **524372**

Subject: Press Release – Orchid Pharma Limited ("the Company")

Dear Sir/Madam,

In accordance to Regulation 30 of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015, read with Schedule III, kindly find enclosed the Press Release being released titled **"Orchid Pharma's 'Exblifep' receives USFDA approval: A new milestone for India's pharmaceutical Industry"**

You are requested to take the above information on your record.

Thanking You,

For **Orchid Pharma Limited**

KAPIL DAYYA
Digitally signed by KAPIL DAYYA
Date: 2024.02.23 15:05:17 +05'30'

Kapil Dayya
Company Secretary & Compliance Officer

Encl: As Above

Press release

Orchid Pharma's 'Exblifep' receives USFDA approval: A new milestone for India's Pharmaceutical industry

- Orchid is the first Indian company to have invented a product approved under the New Drug Application (NDA) process by USFDA
- The European Medicines Agency granted Exblifep approval in January 2024

New Delhi, 23 February 2024: Orchid Pharma, based in Chennai, India, has received approval by the United States Food and Drug Administration (USFDA) for its novel invention, 'Enmetazobactam'. This development comes in close succession to the recent recommendation for approval by the European Medicines Agency (EMA). Enmetazobactam is the first completely invented-in-India Beta Lactamase Inhibitor.

This USFDA approval paves the way for the introduction of Enmetazobactam in the United States, the largest pharmaceutical market in the world. The product is expected to be launched within the next couple of quarters in the US market.

This New Drug Approval (NDA) allows the use of Exblifep (Cefepime and Enmetazobactam) as an injection for the treatment of patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, and Enterobacter cloacae complex.

Orchid is the first company from India, ever to have invented a product which has received a New Drug Approval (NDA) from USFDA. It is a significant development in addressing the global need for affordable and efficacious drugs to combat Anti-Microbial Resistance (AMR).

On this occasion, **Mr. Manish Dhanuka, Managing Director - Orchid Pharma**, said, "While EMA recommendation for grant of marketing authorization last month was a big achievement, the USFDA approval reinforces Orchid's position on the safety of the drug and its innate need in the times of increasing Antimicrobial resistance."

"First discovered in 2008, it has taken 16 years of pain staking work to get the product to market. During this time countless tests were done to establish its safety and efficacy and generate data for submission to regulatory authorities worldwide." he added.

Enmetazobactam was invented in India by Orchid and then out licensed to Allecra Therapeutics for further development. With the potential to save thousands of lives globally, this approval by USFDA is a testament to Indian ingenuity. It is also a matter of great pride that as the pharmacy of the world, India has finally developed a new drug for the first time.

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 under worldwide New Drug Approval Process.

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.

Dhanuka Group acquired Orchid Pharma Ltd. through CIRP (Corporate Insolvency Resolution Process) under IBC (Insolvency and Bankruptcy Code) on 31st March 2020. Since, then the Company has gone through a transformation going from a negative EBIDTA to healthy positive numbers.