September 12, 2023

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

Symbol: **ORCHPHARMA**

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

Scrip Code: **524372**

Subject: Disclosure under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir/Madam,

Pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we would like to inform you that M/s Orchid Pharma Limited has entered into a manufacturing sublicense agreement with Global Antibiotic Research & Development Partnership (GARDP) to manufacture Cefiderocol- an antibiotic to treat certain Gram-negative infections.

In the matter, copy of press release is enclosed herewith.

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

For Orchid Pharma Limited

MARINA PETER
Digitally signed by MARINA PETER
Date: 2023.09.12 12:36:23 +05'30'

Marina Peter
Company Secretary

Critical agreement paves way for new model to accelerate access to important antibiotics for serious bacterial infections

Osaka (Japan), Chennai (India), Geneva (Switzerland), Boston (USA), 12 September 2023—A new agreement is poised to accelerate antibiotic access for tens of thousands of patients in regions with the highest rates of antimicrobial resistance (AMR). The Global Antibiotic Research & Development Partnership (GARDP) and India-based Orchid Pharma Ltd (Orchid) have signed a sublicense agreement to manufacture cefiderocol, an antibiotic to treat certain Gram-negative infections. This agreement is a critical step in an ambitious project by Shionogi & Co. Ltd. (Shionogi), GARDP, and the Clinton Health Access Initiative (CHAI) that aims to provide access to cefiderocol in a number of predominantly low- and middle- income countries.

Launched in June 2022, the project represents a new model for bridging global gaps in equitable access to important antibiotics. Even though populations in low- and middle-income countries face a high burden of death from drug-resistant bacterial infections, their access to antibiotics with activity against resistant bacteria is usually delayed by more than a decade. That situation may worsen given that the number of serious, potentially life-threatening, infections due to carbapenem-resistant bacteria has been growing across multiple regions, including South Asia and Latin America. By addressing barriers that have historically limited the availability of important antibiotics in low- and middle-income countries, this innovative project aims to accelerate appropriate access for an affordable, quality-assured antibiotic to treat drug-resistant Gram-negative infections.

“Access is one of the least talked about issues in the global AMR crisis. This is not just a global market failure but also a public health failure,” said Manica Balasegaram, Executive Director of GARDP. “We can effectively offset the burden of antibiotic resistance by reducing the access gap between high- and lower-income countries so that the right antibiotics are affordable and available for appropriate use. We are proud to work with Orchid to help make this a reality for cefiderocol, and we hope that this project can help pave the way for access to additional antibiotics in the future.”

The licensing agreement signed between Shionogi and GARDP in June 2022 enables GARDP to make cefiderocol available in 135 countries (~70% of countries worldwide, including those with the highest AMR burden), none of which currently has access. Cefiderocol was approved by the US Food and Drug Administration in 2019 and the European Medicines Agency in 2020, and it is on the World Health Organization (WHO) Model List of Essential Medicines (please refer to the detailed US indications and Important Safety Information for cefiderocol found below).

“We are proud to work with Shionogi, GARDP, and CHAI to provide a global solution to access an important antibiotic for areas of need,” said Manish Dhanuka, Managing Director of Orchid Pharma, one of the world’s leading manufacturers of cephalosporin antibiotics. “Our decades-long expertise in cephalosporins will be advantageous in manufacturing affordable and quality-assured cefiderocol. This will address the unmet

needs of patients across low- and middle-income countries where antimicrobial resistance is spreading."

Orchid was selected following a rigorous vetting process led by CHAI with GARDP. The manufacturing sublicense agreement has important access, environmental, and stewardship provisions, including cost-plus pricing, with a commitment to lower the costs based on volumes to help keep the product affordable for patients and health systems in low-resource settings. The sublicense access plan, constituting a part of the sublicense agreement, also stipulates that Orchid will submit the product to the WHO medicines prequalification (PQ) programme. Products listed with WHO PQ are eligible for a collaborative procedure for accelerated registration that reduces the time for national regulatory approvals to 90 days in participating countries. In March 2023, WHO PQ invited manufacturers of cefiderocol to submit expressions of interest, marking the first instance that WHO PQ opened eligibility to products that treat bacterial infections other than tuberculosis.

The signing of the manufacturing sublicense agreement builds on the license agreement between Shionogi and GARDP and on the collaboration agreement between Shionogi, GARDP, and CHAI, both of which were signed in June 2022. Based on these agreements, CHAI will facilitate the technology transfer process between Shionogi and Orchid, and Shionogi will convey essential information for the manufacture of cefiderocol to Orchid, thus accelerating Orchid's ability to manufacture the product and reducing costs that might otherwise be passed on to patients.

"Our work goes beyond researching and developing innovative new medicines to address significant unmet medical needs. We are also focused on developing sustainable programmes, including the critically important agreements with GARDP and CHAI, that focus on significant public health priorities, including access to and appropriate use of antibiotics," said Takuko Sawada, Director and Vice Chairperson of the Board, Shionogi & Co. Ltd. "We welcome Orchid to this programme and are confident that together we will continue to make strides toward increasing access to medications for people living in low- and middle-income countries."

"CHAI is deeply committed to access to appropriate diagnosis and treatment for bacterial infections in people living in low- and middle-income countries. We are excited to bring the tools of market shaping to AMR and to support our partners in delivering this unique project to improve patients' lives," Dr David Ripin, Executive Vice President, Infectious Diseases and Chief Science Officer, CHAI.

In the spirit of transparency and knowledge sharing, and as a baseline for similar agreements in the future, the license agreement and manufacturing sublicense agreement have been published online.

About GARDP

The Global Antibiotic Research & Development Partnership (GARDP) is a Swiss not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. GARDP was created by the World Health Organization and the Drugs for Neglected Diseases initiative (DNDi) in 2016 and legally founded in 2018 to ensure that everyone who needs antibiotics receives effective and affordable treatment. GARDP is funded by the governments of Australia, Germany, Japan, Monaco, the Netherlands, the Public Health Agency of Canada, South Africa, Switzerland, the United Kingdom, the Canton of Geneva, as well as the European Union, Wellcome Trust and private foundations. GARDP is registered under the legal name GARDP Foundation. http://www.gardp.org/

About Orchid

Established in 1992, Orchid Pharma Ltd. (Orchid) is a vertically integrated pharmaceutical company spanning the entire value chain with established credentials in research, manufacturing, and marketing. Orchid is the only Indian pharmaceutical company ever to have invented a New Chemical Entity (NCE, also colloquially called New Drug) which has cleared global clinical phase III trials. The molecule has been submitted for New Drug Approval in the US and Europe. Orchid is a pioneer in the production of quality cephalosporins, especially the sterile products, for which it is one out of few USFDA-approved facilities in the world, and the only one from India. Besides this, Orchid's facilities are approved worldwide, including approvals like EUGMP, PMDA-Japan, and ANVISA-Brazil. www.orchidpharma.com

About Shionogi

Shionogi & Co., Ltd. is a leading global research-driven pharmaceutical company based in Japan dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and well-being of the patients we serve." The company has discovered and developed novel medicines for HIV, influenza and antimicrobial resistance and currently markets products in several therapeutic areas including anti-infectives with the first siderophore cephalosporin. We are working to solve healthcare social issues by identifying disease areas with great social needs as core areas for research and development, with a focus on infectious diseases. For more information on Shionogi & Co., Ltd., visit https://www.shionogi.com/global/en/.

About CHAI

The Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to saving lives and reducing the burden of disease in low- and middle-income countries, while strengthening the capabilities of governments and the private sector in those countries to create and sustain high-quality health systems that can succeed without our assistance. For more information, please visit: http://www.clintonhealthaccess.org.

Other collaborators

GSK

GSK collaborated with Shionogi to develop cefiderocol, and both companies are committed to support access to medicines for patients living in low- and middle-

income countries (LMICs). To help make cefiderocol affordable and available to more people through the Shionogi collaboration with GARDP and CHAI, GSK will forego its royalties from sales in LMICs.

Ping An
Ping An Insurance (Group) Company of China, Ltd. is collaborating with Shionogi to develop cefiderocol in Asia through their joint venture companies, and both companies are committed to supporting access to medicines for patients living in low- and middle-income countries (LMICs). To help make cefiderocol affordable and available to more people in Asia, Ping An Insurance (Group) Company of China, Ltd. supports the Shionogi collaboration with GARDP and CHAI.

About cefiderocol
Cefiderocol for injection is the first and only siderophore cephalosporin antibiotic for the treatment of serious Gram-negative infections. It has a novel mechanism for penetrating the outer cell membrane of Gram-negative pathogens by acting as a siderophore. In addition to entering cells by passive diffusion through porin channels, cefiderocol binds to ferric iron and is actively transported into bacterial cells through the outer membrane via the bacterial iron transporters, which function to incorporate this essential nutrient for bacteria. These mechanisms allow cefiderocol to achieve high concentrations in the periplasmic space where it can bind to penicillin-binding proteins and inhibit cell wall synthesis in the bacterial cells. Cefiderocol has also demonstrated *in vitro* activity against certain bacteria that contain problematic resistant enzymes such ESBLs, AmpC, and serine- and metallo-carbapenemases. Data from multinational surveillance studies for cefiderocol demonstrated potent *in vitro* activity against a wide spectrum of Gram-negative pathogens including carbapenem-resistant *A. baumannii* complex, *P. aeruginosa*, *Enterobacterales*, and *S. maltophilia*. The clinical significance of the *in vitro* data is unknown. Cefiderocol has no clinically relevant *in vitro* activity against most Gram-positive bacteria and anaerobic bacteria.

US INDICATIONS
Fetroja® (cefiderocol) is indicated in patients 18 years of age or older for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa*, and *Enterobacter cloacae* complex.

Fetroja is indicated in patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible Gram-negative microorganisms: *Acinetobacter baumannii* complex, *Escherichia coli, Enterobacter cloacae* complex, *Klebsiella pneumoniae, Pseudomonas aeruginosa*, and *Serratia marcescens*.

USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Fetroja and other antibacterial drugs, Fetroja should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

SELECTED IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Fetroja is contraindicated in patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of Fetroja.

WARNINGS AND PRECAUTIONS

Increase in All-Cause Mortality in Patients with Carbapenem-Resistant Gram-Negative Bacterial Infections

An increase in all-cause mortality was observed in patients treated with Fetroja as compared to best available therapy (BAT) in a multinational, randomized, open-label trial in critically ill patients with carbapenem-resistant Gram-negative bacterial infections (NCT02714595). Patients with nosocomial pneumonia, bloodstream infections, sepsis, or cUTI were included in the trial. BAT regimens varied according to local practices and consisted of 1 to 3 antibacterial drugs with activity against Gram-negative bacteria. Most of the BAT regimens contained colistin.

The increase in all-cause mortality occurred in patients treated for nosocomial pneumonia, bloodstream infections, or sepsis. The 28-Day all-cause mortality was higher in patients treated with Fetroja than in patients treated with BAT [25/101 (24.8%) vs 9/49 (18.4%), treatment difference 6.4%, 95% CI (-8.6, 19.2)]. All-cause mortality remained higher in patients treated with Fetroja than in patients treated with BAT through Day 49 [34/101 (33.7%) vs 10/49 (20.4%), treatment difference 13.3%, 95% CI (-2.5, 26.9)]. Generally, deaths were in patients with infections caused by Gram-negative organisms, including non-fermenters such as *Acinetobacter baumannii* complex, *Stenotrophomonas maltophilia*, and *Pseudomonas aeruginosa*, and were the result of worsening or complications of infection, or underlying comorbidities. The cause of the increase in mortality has not been established.
Closely monitor the clinical response to therapy in patients with cUTI and HABP/VABP.

Click here for Full U.S. Prescribing Information for Fetroja® (cefiderocol).

Media contacts

- GARDP: Aleida Auld, aauld@gardp.org, +41 22 555 19 24
- Orchid Pharma: Mridul Dhanuka, Mridul@orchidpharma.com
- Shionogi: ShionogiCommunications@shionogi.com (US); pressoffice@shionogi.eu (EU); https://www.shionogi.com/global/en/contact.html
- CHAI: Corina Milic, cmilic@clintonhealthaccess.org, +14163716313