PRESSRELEASE

SHIONOGI

New Drug Application of Novel Siderophore Cephalosporin Antibiotics, Cefiderocol, Accepted in China

OSAKA, Japan, August 5, 2024 - Shionogi & Co. Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Ping An-Shionogi Co., Ltd. (Head Office: Shanghai, China; Chairman and CEO: Tatsumori Yoshida, hereafter "Ping An-Shionogi ") filed a New Drug Application (NDA) for cefiderocol to the Center for Drug Evaluation, NMPA (hereafter "CDE") in China, and this application has been accepted for review.

Cefidelocol is a medication that effectively penetrates the outer membrane of gram-negative bacteria, including multidrug-resistant bacteria, and exhibits antimicrobial activity. Cefiderocol is sold in more than 10 countries and regions, including Japan, Europe, and the United States, and has contributed to the treatment of patients suffering from infections caused by drug-resistant bacteria. In addition, cefiderocol is being clinically used in Boao Lecheng International Medical Tourism Pilot Zone, Hainan, China[1].

The current approval application is based on the favorable results of a Phase III clinical trial (hereafter "the trial") conducted with 150 patients with complicated urinary tract infections in China. In the trial, cefiderocol demonstrated superior efficacy compared to the comparator drug, imipenem/cilastatin, and no new safety concerns were identified.

Shionogi has identified "Protect people from the threat of infectious diseases" as a material issue (materiality) to address, and is working towards achieving comprehensive care for infectious diseases. We are committed to protecting the health of people by delivering the necessary infectious disease treatments to patients around the world as quickly as possible, in order to contribute to the successful management of global challenges such as COVID-19 and AMR.

Clich here to learn more about our efforts to address drug resistance.

About AMR

Antimicrobial resistance (AMR) or the acquisition of bacterial resistance to antibiotics, is a global public health threat that humanity faces, and it is an urgent and important issue that needs to be addressed on a global scale[2]. In China, it is estimated that there were 145,500 deaths attributable to AMR and 602,600 deaths associated with AMR in 2019[3]. Those numbers are considered to have been increasing at present.

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 already obtained approval in Europe, United States and Japan and is sold under the product name Fetcroja® in Europe and Fetroja® in the United States and Japan[4]. It is listed on the World Health Organization's Essential Medicines List, and preparations are underway through a collaborative agreement with The Global Antibiotic Research and Development Partnership (GARDP) and Clinton Health Access Initiative (CHAI) to improve access to this new antibacterial agent for patients in many low- and middle-income countries and high- and middle-income countries[5].

References

1. Press release on January 31, 2024
   Cefiderocol is approved for clinical use in Boao Lecheng International Medical Tourism Pilot Zone, Hainan, China
2. WHO. Antimicrobial resistance. Who.int. Published October 13, 2020. https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
3. Global Health Data Exchange (GHDx), The burden of antimicrobial resistance (AMR) in China. The Institute for Health Metrics and Evaluation, Washington University
4. Press release on November 30, 2023
   Regarding the Acquisition of Manufacturing and Marketing Approval for the New Siderophore Cephalosporin Antibiotic Fetroja® (cefiderocol) Intravenous Infusion 1g vial in Japan
5. Press release on June 15, 2022
   Shionogi, GARDP and CHAI announce landmark license and collaboration agreements to treat bacterial infections by expanding access to cefiderocol in 135 countries

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:

SHIONOGI Website Inquiry Form: https://www.shionogi.com/global/en/contact.html