PRESSRELEASE

SHIONOGI

New Siderophore Cephalosporin Antibiotic Fetroja®(cefiderocol) Intravenous Infusion 1g vial Launches in Japan, Along with the Release of Reagents for Antimicrobial Susceptibility Testing

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OSAKA, Japan, December 20, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced the launch of Fetroja®(cefiderocol) intravenous infusion 1g vial in Japan on December 20, 2023. Furthermore, the sale of testing reagents for measuring sensitivity to Cephiderocol will commence on December 22 of this year.

Fetroja®is a new siderophore cephalosporin antibiotic developed by Shionogi. On November 30, 2023, it received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare for various infections caused by strains resistant to carbapenem antibiotics among sensitive strains of *Escherichia coli, Citrobacter species, Klebsiella pneumoniae, Enterobacter species, Serratia marcescens, Proteus species, Morganella morganii, Pseudomonas aeruginosa, Burkholderia species, Stenotrophomonas maltophilia*, and *Acinetobacter species*[1].

As part of our commitment to promoting the proper use of antimicrobial agents, we have been actively working on the development and provision of reagents for drug susceptibility testing to enable prompt testing of bacterial sensitivity to our medication, Fetroja®, since its launch. By establishing a system for drug susceptibility testing concurrently with the release of Fetroja®, we anticipate that this medication will become a new treatment option for appropriate patients suffering from infectious diseases caused by drug-resistant bacteria. This initiative aligns with our dedication to advancing responsible and effective antimicrobial usage.

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.

The impact of this matter on the consolidated financial results for the fiscal year ending March 2024 is expected to be minor.

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

【Fetroja® Product Description】

Product Name	Fetroja®(cefiderocol) Intravenous Infusion 1g vial
Generic Name	Cefiderocol Sulfate Sodium Hydrate for Injection
Indications	Various infections caused by strains resistant to carbapenem antibiotics among sensitive strains of *Escherichia coli, Citrobacter species, Klebsiella pneumoniae, Enterobacter species, Serratia marcescens, Proteus species, Morganella morganii,*

	Pseudomonas aeruginosa, Burkholderia species, Stenotrophomonas maltophilia, and *Acinetobacter species*
Dosage & Administration	For adults, administer Fetroja as a Cefiderocol infusion at a dose of 2g every 8 hours over a period of 3 hours. Adjust the dosage based on renal function.
Date of Manufacturing and Marketing Approval	November 30, 2023
NHI Drug Price Listing Date	December 20, 2023
Date of launch	December 20, 2023
NHI price	Fetroja® Intravenous Infusion 1g, 1 vial, 20,203 yen
Manufacturer and Marketing Authorization Holder	Shionogi & Co., Ltd.

【Antimicrobial Susceptibility Testing Reagent (Research Reagent) Product Description】

Product Name	Shionogi General Bacterial MIC Dry Plates
Intended Use	A kit utilizing liquid medium dilution method designed to measure susceptibility to Cefiderocol
Scheduled Release Date	December 22, 2023
Marketing Authorization Holder	Shionogi & Co., Ltd.

Note: This reagent is intended for research use only and is not approved as an in vitro diagnostic pharmaceutical product. It cannot be used for the purpose of making clinical diagnoses.

About Fetroja®(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 and is sold under the product name Fetcroja® in Europe and Fetroja® in the United States. Approval application has also been completed in Taiwan, and it is currently under review by regulatory authorities[2]. 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[3].

Reference:

1. 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

2. Press release on December 13, 2022
   New Drug Application of New Siderophore Cephalosporin Antibacterial Drug Cefiderocol Accepted for Review in Taiwan
3. 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