



FETROJA® (cefiderocol) Approved by TFDA in Taiwan

OSAKA, Japan, February 22, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Taiwan Shionogi & Co., Ltd., a subsidiary of Shionogi, has received approval from the Taiwan Food and Drug Administration (TFDA) for FETROJA® (cefiderocol) in the treatment of complicated urinary tract infections, including pyelonephritis, and hospital-acquired pneumonia (including hospital-acquired bacterial pneumonia and ventilator-acquired associated bacterial pneumonia) caused by susceptible Gram-negative microorganisms. This approval applies to adult patients.

FETROJA® is a siderophore cephalosporin antibiotic developed by Shionogi, and new drug application in Taiwan was filed on December 13, 2022.¹ FETROJA® exerts its antimicrobial activity by effectively penetrating the outer membrane of gram-negative bacteria, including multidrug-resistant bacteria, through the utilization of the bacteria's iron transport system. FETROJA® has been approved in Japan, Europe, and the United States and is currently being marketed in more than 10 countries and regions^{2,3,4} and is expected to provide a new treatment option for Taiwanese patients suffering from infections caused by drug-resistant bacteria.

Shionogi has identified protecting people from the threat of infectious diseases as a material issue, and is working towards achieving comprehensive care for infectious diseases. As part of this commitment, we are working with The Global Antibiotic Research and Development Partnership (GARDP) and the Clinton Health Access Initiative (CHAI) to provide access to cefiderocol, with proper stewardship, in a wide range of low- and upper-middle-income countries.⁵

[Click here](#) to learn more about our efforts to address the threat of AMR infections.

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 both Europe and United States, and is sold under the product name FETCROJA® in Europe and FETROJA® in the United States. It is listed on the World Health Organization's Essential Medicines List.

About AMR

Antimicrobial resistance (AMR) is a major health burden which urgently needs to be addressed.⁶ Globally, in 2019, there were 1.27 million deaths attributable to bacterial AMR.⁷ Infections caused by carbapenem-

resistant Gram-negative bacteria are often associated with a high mortality rate. If no action is taken, antimicrobial resistance is predicted to kill 10 million people every year by 2050, at a cumulative cost to global economic output of 100 trillion USD.⁸

Reference:

1. [Press release on December 13, 2022](#)
New Drug Application of New Siderophore Cephalosporin Antibacterial Drug Cefiderocol Accepted for Review in Taiwan
2. [Press release on April 28, 2020](#)
SHIONOGI RECEIVES EUROPEAN COMMISSION MARKETING AUTHORISATION FOR FETCROJA[®] (CEFIDEROCOL) FOR THE TREATMENT OF INFECTIONS DUE TO AEROBIC GRAM-NEGATIVE BACTERIA IN ADULTS WITH LIMITED TREATMENT OPTIONS
3. [Press release on November 15, 2019](#)
FETROJA[®] (cefiderocol) Approved by the FDA for Treatment of Complicated Urinary Tract Infections (cUTI) in Adult Patients with Limited or No Alternative Treatment Options
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
6. [Antimicrobial resistance \(who.int\)](#)
WHO. Antimicrobial resistance. Who.int. Published October 13, 2020.
7. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. *Lancet* 2022; 399: 629–55
8. [160525 Final paper with cover.pdf \(amr-review.org\)](#)
O'Neill J. 'Tackling Drug-Resistant Infections Globally: Final Report and Recommendations'. Review on Antimicrobial Resistance. May 2016.

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>