



Launch of the Gram-negative Bacterial Infection Treatment "FETROJA® (Cefiderocol) 1g" in Taiwan

OSAKA, Japan, May 28, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereinafter, "Shionogi") announced that Taiwan Shionogi & Co., Ltd., a subsidiary of Shionogi, had launched sales of FETROJA® (Cefiderocol) (hereinafter, "FETROJA" or "the drug") in Taiwan as of May 27, 2024.

FETROJA is a siderophore cephalosporin antibiotic created by Shionogi. It leverages the bacterial iron transport system to actively penetrate the outer membrane of gram-negative bacteria, including multidrug-resistant strains, and exert its antibacterial activity. In Taiwan, the drug was approved by the Taiwan Food and Drug Administration (TFDA) in February 2024 for the treatment of "complicated urinary tract infections, including pyelonephritis, and hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) in adult patients."^{*1,2} Currently, FETROJA is marketed in more than 10 countries and regions worldwide, including Japan, Europe, and the United States.

Antimicrobial resistance (AMR) is referred to as a "silent pandemic," and without international collaboration and countermeasures, it is projected to cause over 10 million deaths annually by 2050.^{*3} With limited treatment options available, it remains one of the highest unmet medical needs in the infectious disease field. The launch of FETROJA in Taiwan is expected to provide a new treatment option for patients suffering from infections caused by drug-resistant bacteria in the region.

Shionogi has identified "protecting people from the threat of infectious diseases" as a material issue, and is committed to realizing total care for patients with infectious diseases. We will continue our efforts to deliver necessary antimicrobial treatments to patients worldwide as quickly as possible, in order to address the global challenge of AMR.^{*4} Moreover, we will promote the appropriate use of antibiotics, thereby contributing to the treatment of patients with AMR infections and preparing for future threats.

[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 obtained approval in Japan, Europe, and the United States, and is marketed under the brand name "Fetroja®" in Japan and the United States, and "Fetcroja®" in Europe. Fetroja is also listed on the WHO Essential Medicines List. Furthermore, to improve access for patients in many low- and middle-income countries as well as high- and middle-income countries, preparations are underway through a tripartite agreement with The Global Antibiotic Research and Development Partnership (GARDP) and the Clinton Health Access Initiative (CHAI).^{*4}

Reference:

1. [New Drug Application of New Siderophore Cephalosporin Antibacterial Drug Cefiderocol Accepted in Taiwan](#)
2. [FETROJA \(cefiderocol\) Approved by TFDA in Taiwan](#)
3. O'Neill J. 'Tackling Drug-Resistant Infections Globally: Final Report and Recommendations'. Review on Antimicrobial Resistance. May 2016. Retrieved from https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf
4. [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>