



Approval for "Fetroja®" (cefiderocol) in South Korea

OSAKA, Japan, February 21, 2025 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") is pleased to announce that JEIL PHARMACEUTICAL CO., LTD. (Headquarters: Seoul, South Korea; President: Suk Je Sung ; hereinafter "JEIL"), its partner in South Korea¹, has obtained marketing approval from the South Korean regulatory authorities for the gram-negative bacterial infection treatment "Fetroja®" (cefiderocol) (hereafter "Fetroja").

Fetroja®/Fetcroja® (cefiderocol), an innovative siderophore cephalosporin, for the treatment of critically ill patients with carbapenem-resistant (CR) Gram-negative (GN) bacterial infections. In South Korea, based on the results of three global clinical trials (a Phase 2 trial [APEKS-cUTI] in patients with complicated urinary tract infections, a Phase 3 trial in patients with carbapenem-resistant gram-negative bacterial infections [CREDIBLE-CR], and a Phase 3 trial in patients with nosocomial pneumonia [APEKS-NP])²⁻⁴, JEIL received marketing approval.

Antimicrobial resistance (AMR), the phenomenon where bacteria acquire resistance to antibiotics, is one of the most significant global public health threats facing humanity and requires urgent action. AMR has been referred to as a "silent pandemic," and without countermeasures, it is projected to result in over 10 million deaths annually by 2050⁵. However, available treatment options remain limited, making this an area of high unmet medical need. With this approval, Fetroja will be a new treatment option for patients in South Korea suffering from infections caused by multidrug-resistant.

Shionogi has identified "Protecting people from the threat of infectious diseases" as a material issue (materiality) to address, and is working toward 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.

About Shionogi in AMR

Shionogi has a strong heritage in the field of anti-infectives and has been developing antimicrobial therapies for more than 60 years. Shionogi is proud to be one of the few large pharmaceutical companies that continues to focus on R&D in anti-infectives. [Click here](#) to learn more about our efforts to address drug resistance.

About Cefiderocol

In Europe, cefiderocol is commercially available under the brand name Fetcroja® for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options⁶. In the U.S., cefiderocol is available under the brand name Fetroja® and is indicated in patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia (HABP/VABP) and complicated urinary tract infections (cUTIs) caused by certain susceptible Gram-negative microorganisms⁷. In Japan, cefiderocol is commercially available under the brand name Fetroja® and 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 species⁸.

Cefiderocol is listed on the World Health Organization's Essential Medicines List⁹, 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 countries¹⁰.

About JEIL PHARMACEUTICAL CO., LTD.

Founded in 1959 and listed on KOSPI since 1988, JEIL has consistently contributed to the growth and development of South Korea's pharmaceutical industry by developing and supplying high-quality medicines. Today, JEIL collaborates with pharmaceutical companies worldwide and is recognized as an advanced pharmaceutical company that adheres to international business practices.

Reference:

1. [Press release on July 28, 2022](#) Execution of Sublicense Agreement with JEIL for New Siderophore Cephalosporin Antibacterial Drug Cefiderocol in South Korea
2. [Press release on January 12, 2017](#)
3. [Press release on October 2, 2019](#)
4. [Press release on November 15, 2019](#)
5. 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
6. Fetroja[®] Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/fetroja-epar-product-information_en.pdf. Accessed: March 2024.
7. Fetroja[®] Prescribing information. Available at: <https://www.shionogi.com/content/dam/shionogi/si/products/pdf/fetroja.pdf> Accessed: April 2024.
8. [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
9. WHO Model List of Essential Medicines - 23rd list, 2023. [WHO Model List of Essential Medicines - 23rd list, 2023](#) Accessed: April 2024
10. [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.

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