



New Drug Application of New Siderophore Cephalosporin Antibacterial Drug Cefiderocol Accepted for Review in Taiwan

OSAKA, Japan, December 13, 2022 - 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, filed a New Drug Application (NDA) for cefiderocol, a new siderophore cephalosporin antibacterial drug, to the TFDA (Taiwan Food and Drug Administration) for the treatment of infections due to aerobic Gram-negative bacteria in adult patients with limited treatment options, and this application has been accepted for review by TFDA.

Antimicrobial resistance (AMR) has been called the "silent pandemic" and is an urgent and important public health threat. It is estimated to cause over 10 million deaths by 2050 if approaches through international cooperation to address AMR will not change¹. The number of effective medicines available for AMR bacterial infections are limited. If approved in Taiwan, cefiderocol would become a new treatment option for patients in Taiwan suffering from AMR bacterial infections.

Cefiderocol has been approved in the United States and Europe and is currently marketed in seven countries^{2,3}. In order to contribute to the treatment of patients with AMR bacterial infections and to prepare for future threats, Shionogi is in discussions with regulatory authorities regarding development and approval review in Taiwan, Japan, China, and other countries. In addition, Shionogi will work with The Global Antibiotic Research and Development Partnership (GARDP) and Clinton Health Access Initiative (CHAI) to improve access for patients in need of cefiderocol in a wide range of low- and upper-middle-income countries⁴.

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as our key focus. We pursue not only the research and development of therapeutic medications, but also total care for infectious disease. To support addressing the scourge of AMR beyond the provision of our own products, we participate in the R&D support fund and are working with governments to develop new, more viable, approaches for the reimbursement of anti-infective products. Shionogi is committed to fighting the AMR globally, in part by urgently developing and providing infectious disease drugs required to protect the health of patients around the world.

For more information about our commitment to AMR, please check <https://www.shionogi.com/global/en/sustainability/amr.html>.

About cefiderocol

Cefiderocol is the first and only siderophore cephalosporin antibiotic for the treatment of serious Gram-negative infections. It has a novel mechanism that allows it to penetrate 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 accumulate 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. Cefiderocol has also demonstrated in vitro activity against certain bacteria that contain problematic resistance enzymes such as ESBLs, AmpC, and serine- and metallo-carbapenemases. Data from multinational surveillance studies for cefiderocol demonstrated potent in vitro activity against a wide spectrum of Gram-negative pathogens, including carbapenem-resistant *A. baumannii* complex, *P. aeruginosa*, enterobacterales and *S. maltophilia*. The clinical significance of the in vitro data is unknown. Cefiderocol has no clinically relevant in vitro activity against most Gram-positive bacteria and anaerobic bacteria. Cefiderocol was approved and launched in the United States (product name: FETROJA®) in November 2019 and in Europe (product name: FETCROJA®) in April 2020^{2,3}.

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.

Reference

1. 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
2. [February 25, 2020 Press Release](#)
Shionogi's FETROJA® (cefiderocol) Now Available for the Treatment of Complicated Urinary Tract Infections in the U.S.
3. [April 28, 2020 Press Release](#)
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
4. [June 15, 2022 Press Release](#)
Shionogi, GARDP and CHAI announce landmark license and collaboration agreements to treat bacterial infections by expanding access to cefiderocol in 135 countries
5. [June 16, 2022 Press Release](#)

SHIONOGI SIGNS AGREEMENT WITH NHS ENGLAND TO BEGIN AN INNOVATIVE SUBSCRIPTION PAYMENT MODEL FOR REIMBURSEMENT OF ITS ANTIBIOTIC, FETCROJA® (CEFIDEROCOL)

6. [July 28, 2022 Press Release](#)

Execution of Sublicense Agreement with JEIL for New Siderophore Cephalosporin Antibacterial Drug Cefiderocol in South Korea

7. [October 20, 2022 Press Release](#)

Shionogi Presents Real-World Evidence Showing Strong Efficacy with Fetroja® (cefiderocol) Against Treatment Resistant Bacterial Infections at IDWeek 2022

For Further Information, Contact:

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