



Exclusive Licensing Agreement with Link Healthcare, a Clinigen Company for Cefiderocol in Australia and New Zealand

OSAKA, Japan, April 2 , 2025 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereinafter "Shionogi") is pleased to announce that it has entered into an exclusive licensing agreement with Link Medical Products Pty Ltd (hereinafter "Link"), part of Clinigen, the global specialty pharmaceutical services group (Senior Vice President - JAPAC: Dr. Varun Sethi; hereinafter "Clinigen") for the development and commercialization of cefiderocol in Australia and New Zealand. The Therapeutic Goods Administration (TGA) regulatory authority in Australia accepted the market authorisation application for cefiderocol in December 2024 and the application is under evaluation¹.

Under the terms of the agreement, Link will in-license cefiderocol from Shionogi and obtain exclusive rights for its development and commercialization in Australia and New Zealand. Shionogi will receive an upfront payment, milestone payments based on development progress, and royalties from Link.

Shionogi is committed to research and development of innovative treatments for infectious diseases for the benefit of patients around the world and to helping tackle urgent global health challenges such as antimicrobial resistance (AMR).

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 options². 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 microorganisms³. 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 species*⁴. Cefiderocol is listed on the World Health Organization's Essential Medicines List⁵, 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 antibacterial agent for patients in low- and middle-income countries⁶.

About AMR

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 2050^{7,8}

[Click here](#) to learn more about our efforts to address drug resistance.

About Link Medical Products Pty Ltd

For almost 30 years, Link Healthcare, part of the Clinigen Group, has played a vital role in the Australasian healthcare landscape as a trusted partner providing ethical and compliant pathways to both registered and unregistered medicines. With a team of 58 employees, Link Healthcare offers specialised pharmaceutical services across the product lifecycle, from clinical through to commercial, supporting pharmaceutical and biotech companies and healthcare professionals to address unmet patient needs.

For more information on Link Healthcare, a Clinigen Company visit: <https://www.linkhealthcare.com.au>

About Clinigen

Clinigen is a global, specialist pharmaceutical services company focused on providing ethical access to medicines. Its mission is to accelerate access to medicines for patients in every corner of the globe. The Group supports pharmaceutical and biotech companies across the medical product lifecycle, from clinical through to commercial and operates from sites in North America, Europe, Africa and the Asia Pacific. Clinigen has more than 1,100 employees across five continents in 15 countries and provides access in more than 130 countries every year.

For more information on Clinigen, please visit <http://www.clinigen.com>.

Reference:

1. [Acceptance of a New Drug Application for the Gram-Negative Bacterial Infection Treatment, Cefiderocol, in Australia | SHIONOGI](#)
2. 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.
3. Fetroja[®] Prescribing information. Available at: [Full U.S. Prescribing Information for Fetroja[®] \(cefiderocol\)](#). Accessed August 2024.
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. WHO Model List of Essential Medicines - 23rd list, 2023. [WHO Model List of Essential Medicines - 23rd list, 2023](#) Accessed: April 2024
6. [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
7. [Global antimicrobial resistance forum launched to help tackle common threat to planetary health](#)
8. 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

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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