PRESSRELEASE

SHIONOGI

Approval for Cefiderocol in Australia

OSAKA, Japan, September 7 2026 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced today that it has received marketing authorization from the Therapeutic Goods Administration (TGA) in Australia for cefiderocol, a siderophore cephalosporin developed by Shionogi for the treatment of carbapenem-resistant Gram-negative bacterial infections.

This marketing authorization is based on the results of three global clinical trials of cefiderocol conducted to date: the Phase 2 APEKS-cUTI study in patients with complicated urinary tract infections (cUTI), the Phase 3 CREDIBLE-CR study in patients with carbapenem-resistant Gram-negative bacterial infections, and the Phase 3 APEKS-NP study in patients with hospital-acquired pneumonia.[1-3] The TGA has approved cefiderocol for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia due to proven or strongly suspected carbapenem-resistant aerobic Gram-negative organisms in adults with limited treatment options. Shionogi has entered into a license agreement with Link Medical Products Pty Ltd (Head Office: New South Wales, Australia; hereafter "Link") for the development and commercialization of cefiderocol in Australia and New Zealand.[4] Following the marketing authorization in Australia, Shionogi will work with Link to improve access to this novel antibacterial agent for patients who need it.

Antimicrobial resistance (AMR), often referred to as a "silent pandemic," is one of the major global public health threats facing humanity and is an urgent global challenge that requires immediate action. In 2021, AMR was estimated to have been directly responsible for 1.14 million deaths worldwide, and it is projected that more than 39 million people could die from AMR by 2050 unless action is taken through international collaboration.[5-7] At the same time, treatment options remain limited, making AMR one of the areas with a significant unmet medical need. Cefiderocol is active against Gram-negative bacteria, including a range of multidrug-resistant bacteria that have become difficult to treat due to the acquisition of antimicrobial resistance, and the marketing authorization is expected to provide a new treatment option for patients with these infections.

Shionogi has identified "Protect People from the Threat of Infectious Diseases" as one of its material issues and is advancing initiatives toward realizing total care for infectious diseases. To contribute to the successful global response to AMR, Shionogi will continue its efforts to deliver anti-infective medicines needed to protect people's health to patients around the world.

For more information on Shionogi's initiatives to address AMR, please visit Address the problem of antimicrobial resistance (AMR).

About Cefiderocol

Cefiderocol is an antibacterial agent that effectively penetrates the outer membrane of Gram-negative bacteria, including multidrug-resistant bacteria, to exert its antibacterial activity. The APEKS-cUTI is a global, double-blind, parallel-group Phase 2 study, the CREDIBLE-CR is a global, open-label, parallel-group phase 3 study, the APEKS-NP is a global, double-blind, parallel-group Phase 3 study. Cefiderocol is marketed in multiple countries and regions, including the United States, Japan, Europe, Taiwan, and South Korea.
Cefiderocol is included in the World Health Organization (WHO) Model List of Essential Medicines and plays an important role globally as a treatment option for infections caused by antimicrobial-resistant bacteria. To improve access to this novel antibacterial agent for patients in need across many low- and middle-income countries, Shionogi is also advancing initiatives through a tripartite agreement with the Global Antibiotic Research and Development Partnership (GARDP) and the Clinton Health Access Initiative (CHAI).[8]
The application for marketing authorization in Australia was accepted by the Australian authorities in December 2024.[9] Cefiderocol is not currently listed on the Pharmaceutical Benefits Scheme. For more information about cefiderocol in Australia, healthcare professionals and consumers should consult the Consumer Medicine Information. Cefiderocol is included in the Black Triangle Scheme and subject to additional monitoring. Healthcare professionals are asked to report suspected adverse events to the TGA.[10]
It is recommended that cefiderocol should be used after consultation with a physician with appropriate experience in the management of infectious diseases.

About Link Medical Products Pty Ltd

For over 30 years, LINK Healthcare, part of Clinigen, has been a trusted partner to healthcare professionals, hospitals, pharmaceutical and biotechnology companies across Australia and New Zealand. Providing specialised services across the product lifecycle, from clinical development through to commercialisation, LINK enables ethical and compliant access to registered and unregistered medicines.

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.

References:

1. Press release on January 12, 2017
2. Press release on October 2, 2019
3. Press release on November 15, 2019
4. Press release on April 2, 2025
5. GBD 2021 Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance 1990-2021: a systematic analysis with forecasts to 2050. Lancet. 2024 Sep 28;404(10459):1199-1226. doi: 10.1016/S0140-6736(24)01867-1. Epub 2024 Sep 16. PMID: 39299261.
6. World Health Organization (WHO), "Antimicrobial resistance," 16 July 2026.
7. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet 2022; 399: 629−55.
8. Press release on June 15, 2022
9. Press release on December 3, 2024
10. Report an adverse event or safety problem | Therapeutic Goods Administration (TGA)

For Further Information:

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