



## **Acceptance of a New Drug Application for the Gram-Negative Bacterial Infection Treatment, Cefiderocol, in Australia**

**OSAKA, Japan, December 03, 2024** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereinafter, "Shionogi") is pleased to announce that our new drug application for cefiderocol, an innovative treatment for gram-negative bacterial infections, has been accepted by the Therapeutic Goods Administration (TGA) in Australia.

Cefiderocol has completed three global 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])<sup>1-3</sup>, and the acceptance of this application is based on the results obtained from these trials.

Cefiderocol is a potent antibacterial agent that effectively penetrates the outer membrane of gram-negative bacteria, including multidrug-resistant strains. It is currently marketed in 25 countries and regions, including Japan, Europe, the United States, and Taiwan (trade names: Fetroja® in the United States and Taiwan, Fetcroja® in Europe, and Fetroja® in Japan)<sup>1-3</sup>, and multiple real-world data studies highlighting its effectiveness in treating severe patients have been published.<sup>4,5</sup> In addition, cefiderocol is listed on the World Health Organization's Essential Medicines List.\*

\* A list of minimum medicine needs for a basic health-care system, comprising the most efficacious, safe, and cost-effective medicines for priority conditions.

Shionogi has identified "Protecting people from the threat of infectious diseases" as a material issue 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 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 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. Its preparations are under way through a collaborative agreement with the Global Antibiotic Research and Development Partnership (GARDP) and the Clinton Health Access Initiative (CHAI) to improve access to this new antibacterial agent for patients in many low- and middle-income countries, as well as high- and middle-income countries<sup>6</sup>.

## About AMR

Antimicrobial resistance (AMR) or the acquisition of bacterial resistance to antibiotics, is a global public health threat that humanity faces, and is an urgent and important issue that needs to be addressed on a global scale.<sup>7,8</sup> In 2019, it was estimated that 1.27 million people worldwide lost their lives due to antimicrobial resistance (AMR).<sup>8</sup> Furthermore, unless international cooperation is established to address this issue, it is predicted that by 2050, more than 10 million people could die annually as a result of AMR, with the cumulative impact on the global economy potentially reaching up to 100 trillion USD.<sup>9</sup>

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

## 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 October 16, 2024](#)
5. [Press release on April 19, 2024](#)
6. [Press release on June 15, 2022](#)
7. [Antimicrobial resistance \(who.int\)](#) WHO. Antimicrobial resistance. Who.int. Published October 13, 2020.
8. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. *Lancet* 2022; 399: 629–55
9. [160525\\_Final\\_paper\\_with\\_cover.pdf \(amr-review.org\)](#)  O'Neill J. 'Tackling Drug-Resistant Infections Globally: Final Report and Recommendations'. Review on Antimicrobial Resistance. May 2016.

## 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>