PRESSRELEASE

SHIONOGI

ESCMID Global 2026: Shionogi presents new real-world data highlighting clinical effectiveness of Fetroja®/Fetcroja® (cefiderocol) in MBL-producing Enterobacterales infections

- Real world evidence study carried out in Spain demonstrates 68% clinical cure rate at day 14, and 83% overall survival at day 28, for patients infected with highly resistant metallo-beta lactamase (MBL)-producing pathogens[1]
- Carbapenem-resistant Enterobacterales pathogens are considered by the World Health Organization to be one of the most critical health threats[2]

OSAKA, Japan, 7th April , 2026 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") presents new real-world data evaluating Fetroja®/Fetcroja® (cefiderocol), an innovative siderophore cephalosporin, in adults with confirmed MBL-producing Enterobacterales infections at the 36th Congress of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in Munich,17th-21st April, 2026[1].

The CIRCE study was a retrospective, observational, multicentre study conducted in Spain between January 2023 and April 2025, designed to describe the efficacy of real-world cefiderocol use in 232 adult patients with infections caused by MBL-producing Enterobacterales[1].

The analysis found 68% of patients who received cefiderocol were considered clinically cured at day 14 and 82% of patients achieving a positive clinical response at day 14[1]. The overall rates of survival at days 14 and 28 were 90% and 83%, respectively, in this population[1]. At baseline, 29% of patients were immunosuppressed, 27% were in intensive care and 13% presented with septic shock[1].

MBL-producing Enterobacterales inactivate almost all beta-lactam antibiotics, including carbapenems - agents typically reserved for severe or high-risk infections, thereby limiting therapeutic options[3,4]. In the CIRCE study, the most frequently identified pathogens were carbapenem-resistant *Klebsiella pneumoniae* and *Enterobacter* spp. respectively[1], both classified by the World Health Organization as critical priority pathogens due to their high levels of resistance to currently available therapies[2].

Dr Ricard Ferrer, Head of the Intensive Care Department at Vall d'Hebron Hospital in Barcelona, Spain, said: "MBL-producing Enterobacterales infections represent a significant and growing clinical challenge worldwide, particularly in critically ill patients where treatment options are limited. These data support the clinical effectiveness of cefiderocol in adult patients with these infections, contributing further real-world evidence to inform future treatment considerations in practice."

Among patients with available follow-up cultures, microbiological eradication rates were reported as 85% in bloodstream infections and 82% in urinary tract infections (UTIs)[1]. Approximately half of patients received cefiderocol based on the results of susceptibility testing[1].

Additional data presented at ESCMID 2026 evaluated the *in vitro* activity of cefiderocol against over 4000 *Stenotrophomonas maltophilia* clinical isolates collected through the multinational SIDER0-WT (2014–2019) and SENTRY (2020–2024) surveillance programmes[5]. Across this ten-year period, cefiderocol demonstrated consistently high activity, with no significant change in susceptibility observed before or after market introduction[5]. *Stenotrophomonas maltophilia* is an opportunistic pathogen with intrinsic resistance to multiple antimicrobial classes, often limiting treatment options in high-risk patients[5].

Data presented at the same congress reinforced cefiderocol's efficacy against *Stenotrophomonas maltophilia*, with a subgroup analysis of 119 patients from the PROVE study demonstrating clinical cure in approximately two-thirds of patients, the majority of whom were critically ill and receiving care in intensive care units[6].

Dr Mark Hill, global head of medical affairs at Shionogi, said: "Antimicrobial resistance continues to threaten effective treatment of serious Gram-negative infections globally. These data add to the growing body of evidence supporting cefiderocol in resistant pathogens and underscores the importance of sustained investment in innovation and evidence generation in antimicrobials."

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About Shionogi & Co. Ltd.

Shionogi & Co., Ltd. is a 148-year-old global, research-driven pharmaceutical company headquartered in Osaka, Japan, that is dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and wellbeing of the patients we serve." The company currently markets products in several therapeutic areas including anti-infectives, pain, CNS disorders, cardiovascular diseases. Shionogi's research and development currently target two therapeutic areas: infectious diseases, and diseases with unmet medical needs in pain/CNS, including Alzheimer's disease, oncology, rare diseases, and sleep apnea. For more information on Shionogi & Co., Ltd., please visit https://www.shionogi.com/global/en.

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.

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 options[7]. In the US, cefiderocol is commercially available under the brand name Fetroja® for the treatment of patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia and complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms[8] 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*[9].

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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