PRESSRELEASE

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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, April 8, 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® (Generic name：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, multicenter chart review study conducted in Spain between January 2023 and April 2025, designed to describe the effectiveness and safety 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 achieved 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] Drug associated adverse events were collected through routine chart review with no new identified safety signals beyond the established safety profile of cefiderocol.[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.[1,3,4] 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]

"MBL-producing Enterobacterales infections represent a significant and growing clinical challenge worldwide, particularly in critically ill patients where treatment options are limited," said Dr Ricard Ferrer, Head of the Intensive Care Department at Vall d'Hebron Hospital in Barcelona, Spain. "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 susceptibility testing.[1]

Additional data presented at ESCMID 2026 evaluated the in vitro* activity of cefiderocol against more than 4,000 *Stenotrophomonas maltophilia* clinical isolates collected through the multinational SIDERO-WT (2014–2019) and SENTRY (2020–2024) surveillance programmes. [5] Across this ten-year period, there was no significant change in cefiderocol susceptibility observed before or after market introduction.[6] *Stenotrophomonas maltophilia* is an opportunistic pathogen with high intrinsic resistance to multiple antimicrobial classes, often limiting treatment options in high-risk patients.[5]

Data presented at the same congress reinforced cefiderocol's effectiveness 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]

"Antimicrobial resistance continues to threaten effective treatment of serious Gram-negative infections globally," said Mark Hill, Global Head of Medical Affairs, Shionogi & Co. Ltd. "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."

**In vitro activity does not necessarily correlate with clinical efficacy.*

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 and 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 Infectious Disease

Over the past 70 years, Shionogi has discovered and commercialized six novel antibiotics. Today, our R&D story extends beyond antibiotics to include novel medications for HIV and influenza. Our global pipeline includes investigational agents to address global health challenges including antimicrobial resistance, COVID-19, influenza, rare fungal diseases and respiratory syncytial virus.

As part of our commitment to addressing unmet medical needs, Shionogi partners with several non-governmental organizations to increase equitable access to our medications worldwide. Shionogi and Global Antibiotic Research and Development Partnership (GARDP) have a license and technology transfer agreement and Shionogi and GARDP have a collaboration agreement with the Clinton Health Access

Initiative (CHAI) that aim to transform the landscape of access to antibiotics in many low-income countries, most lower middle- and upper middle-income countries, and select high-income countries.

Shionogi's ongoing efforts to address current and emerging health threats includes a U.S.-based drug discovery laboratory in the U.S. with Qpex Biopharma, Inc., a Shionogi Group Company. Through Qpex, we are advancing a robust portfolio of potential best-in-class, clinical-stage antimicrobial compounds. Learn more about the Qpex lab here.

Shionogi ranked #2 among large research-based pharmaceutical companies in the Access to Medicine Foundation's 2026 Antimicrobial Resistance (AMR) Benchmark, a global assessment of how leading pharmaceutical companies are tackling antimicrobial resistance and expanding responsible access to antibiotics worldwide.

About Cefiderocol

In the U.S., cefiderocol is commercially 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 and complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms.[3] 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 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.

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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