PRESSRELEASE

SHIONOGI

ESCMID Global 2025: Shionogi presents real-world data demonstrating better clinical outcomes when Fetcroja® / Fetroja® (cefiderocol) is used as empiric or documented therapy as compared to salvage therapy for the treatment of Gram-negative bacterial infections

- *Data from five European countries demonstrates the effectiveness of cefiderocol against Gram-negative pathogens considered as high or critical priorities by the WHO, including high rates of clinical cure and day 28 survival across patients with limited treatment options.*[1,2]
- *New European cohort data from the largest real-world evidence study of cefiderocol indicates a lower clinical cure rate trend among patients who received cefiderocol as salvage therapy compared with patients who received documented or empirical treatment.*[3]

OSAKA, Japan, 8th April , 2025 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") presents new European data from its largest real-world evidence study of Fetroja®/Fetcroja® (cefiderocol), an innovative siderophore cephalosporin at the 35th Congress of the European Society of Clinical Microbiology and Infectious Diseases in Vienna on 11th-15th April 2025.

The PROVE (Retrospective Cefiderocol Chart Review) study is a five-year international, retrospective, observational medical chart review study, conducted between November 2020 and July 2024 designed to describe the efficacy and safety of real-world cefiderocol use in adult patients with serious Gram-negative (GN) bacterial infections.[1]

Analysis of the European cohort found a higher clinical cure rate trend among patients who received cefiderocol for a documented infection (67.4%) or as empiric therapy (64.6%) as compared to those who received it as salvage therapy (58.2%).[3]

Professor Oliver Cornely, Director of Translational Research, University of Cologne, said: "These data suggest a trend towards worse clinical outcomes when the use of cefiderocol to treat Gram-negative bacterial infections is reserved as a last line treatment option compared with those who received the treatment earlier. This trend may offer clinicians new evidence to justify the early and effective use of cefiderocol in patients with suspected resistant infections."

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The study analysed data from 567 patients hospitalised with confirmed GN bacterial infections, who were treated with cefiderocol for the first time for ≥72 hours across Spain, France, Italy, Germany and the United Kingdom.[1] Carbapenem resistance rate was >70% among patients enrolled in the study.[1] 55.9% of patients were critically ill in the intensive care unit and 41.3% were receiving organ support at the point of cefiderocol initiation.[1]

Respiratory tract infection (RTI) was the most frequent infection site, reported in over 50% patients (299), followed by urinary tract infection in over 12% of patients (73).[1]

Patients in the study receiving cefiderocol across all pathogens achieved an overall clinical cure rate of 65.3%.[1] The most frequent pathogens observed were *Pseudomonas aeruginosa* (41.3%), *Acinetobacter baumannii* (15.0%), and Enterobacterales (14.6%)[1], which are identified as priority pathogens by the World Health Organisation[2]. A clinical cure rate of 73.1% was observed among patients with a *Pseudomonas aeruginosa* infection.[1]

Takuko Sawada, Board Director and Vice Chair, Shionogi & Co Ltd., said: "Antimicrobial resistance is one of the most pressing global health challenges of this century, resulting in the deaths of millions of people around the world each year. In order to support better patient outcomes, it is imperative that clinicians have access to the innovative treatments they need for appropriate use with the right patient at the right time. We remain committed to the research and development of essential medicines that will help tackle the growing threat of drug-resistant infection."

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About Shionogi & Co. Ltd.
Shionogi & Co., Ltd. is a 147-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 and gastroenterology. Shionogi's research and development currently target two therapeutic areas: infectious diseases, and pain/CNS disorders.

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.[4] 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.[5] 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.*[6]

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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References

[1] Asensio Martin JM et al. Cefiderocol treatment in patients with Gram-negative bacterial infections: European results of the global retrospective observational PROVE study. Abstract. ESCMID 2025.

[2] WHO Bacterial Priority Pathogens List, 2024: Bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance.

[3] Asensio Martin JM et al. Cefiderocol treatment in patients with Gram-negative bacterial infections: European results of the global retrospective observational PROVE study. Poster 2542. ESCMID 2025.

[4] Fetcroja® Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/fetcroja-epar-product-information_en.pdf . Accessed: March 2024.

[5] Fetroja® Prescribing information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209445s000lbl.pdf. Accessed: March 2024.

[6] 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