



IDWeek 2026: Shionogi Presents U.S. Analysis of Real-World Data Showing Early Treatment Initiation with Fetroja®/Fetcroja® (cefiderocol) Improved Clinical Outcomes in Patients with Respiratory Infections

- Rapid Fire session will feature new data from the SENTRY Global Antimicrobial Surveillance Program demonstrating potent *in vitro* activity of cefiderocol against *Pseudomonas aeruginosa* in ventilator-associated pneumonia (VAP)
- New systematic literature review summarizes cefiderocol use in infections caused by *Stenotrophomonas maltophilia*, a pathogen for which IDSA [2026 AMR Guidance](#) lists cefiderocol as a preferred treatment

OSAKA, Japan, October 21, 2026 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") will present new data at IDWeek 2026 that reinforce the role of Fetroja®/Fetcroja® (cefiderocol), an innovative siderophore cephalosporin, in serious Gram-negative infections.

Cefiderocol data highlights at IDWeek will include new U.S. real-world data demonstrating improved clinical outcomes with early cefiderocol treatment versus salvage therapy in critically ill patients with respiratory infections caused by carbapenem-resistant Gram-negative bacteria. Shionogi will also present global surveillance data showing cefiderocol maintained greater than 90% CLSI susceptibility against highly resistant *P. aeruginosa* VAP isolates despite resistance to other newer beta-lactam/beta-lactamase inhibitor (BL/BLI) combinations, and a systematic literature review summarizing the published evidence supporting the use of cefiderocol in vulnerable high-risk patients with infections caused by *S. maltophilia*.¹⁻³

Cefiderocol is approved in the U.S. for the treatment of adult patients with complicated urinary tract infections (cUTIs), including pyelonephritis, and hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by certain susceptible Gram-negative bacteria. See Fetroja U.S. full indications and important safety information below in the About Cefiderocol section.⁴

PROVE Data Support Early Cefiderocol Use in Critically Ill Patients with Carbapenem-Resistant Respiratory Infections

PROVE (Retrospective Cefiderocol Chart Review) is an international, retrospective, observational medical chart review study conducted between November 2020 and July 2024 in more than 1,000 patients in the

U.S. and Europe.^{1,5} The subgroup analysis that will be presented at IDWeek evaluated 266 U.S. patients treated with cefiderocol for respiratory tract infections caused by Gram-negative bacteria, of which 89.5% (n=238) were resistant to carbapenem antibiotics.¹

In the study, 59.4% of patients (n=158) were male, 35% of patients (n=93) had chronic pulmonary disease and nearly all patients (96.6%) had one or more risk factors for carbapenem-resistant Gram-negative bacteria infections.¹ The median hospital stay for these patients was 42.0 days, and almost three-quarters of patients (74.8%) were in the intensive care unit, and two-thirds (65.4%) received organ support and/or mechanical ventilation (66.2%).¹

Cefiderocol was administered for a median duration of 9.0 days (IQR: 7.0–14.0), and most patients (72.9%) received cefiderocol once the pathogen and susceptibility profile were known.¹ The majority (66.5%) of infections were monomicrobial, and the most frequently observed pathogens were *P. aeruginosa* (34.2%; n=91) and *Acinetobacter baumannii* (19.2%; n=51).¹

In this subgroup analysis of 266 patients, the overall clinical response rate was 76.7% (n=204), for patients receiving cefiderocol.¹ Clinical response was achieved in 78.9% (n=153/194) of patients treated after the pathogen and its antibiotic susceptibility were known, 80.0% (n=24/30) of patients who started cefiderocol empirically prior to pathogen identification and 63.4% (n=26/41) of patients who received cefiderocol after a prior antibiotic regimen had failed.¹

“We conducted this sub analysis because hospital-acquired respiratory tract infections caused by carbapenem-resistant Gram-negative bacteria are difficult to treat, and delayed antibiotic treatment can be associated with increased morbidity and mortality,” said Amy L. Carr, PharmD, BCIDP at AdventHealth Orlando. “These real-world findings provide important insight into the treatment of critically ill patients with respiratory infections caused by carbapenem-resistant Gram-negative bacteria. Notably, the use of cefiderocol earlier in the treatment course was associated with higher clinical response rates than when cefiderocol was used after a prior antibiotic regimen had failed.”

As Antimicrobial Resistance Among *P. Aeruginosa* Continues to Increase and Treatment Options Become More Limited, SENTRY Global Antimicrobial Surveillance Program Data Presented During a Rapid-Fire Session Reinforce Cefiderocol’s *In Vitro* Activity Against Isolates from Patients with Ventilator-Associated Pneumonia (VAP)

The SENTRY Antimicrobial Surveillance Program monitors pathogen prevalence and antimicrobial susceptibility patterns worldwide.^{2,6} Surveillance programs like SENTRY track how bacterial resistance evolve over time and across regions, offering critical early warnings of emerging strains and helping guide clinical treatment decisions.^{2,6}

Shionogi will present SENTRY Surveillance Program data evaluating cefiderocol against 1,400 global *P. aeruginosa* isolates collected from patients with VAP in the U.S. and Europe between 2020-2024.² *P. aeruginosa* is a leading cause of VAP and a significant driver of mortality in critically ill patients.²

The study compared cefiderocol with four commonly prescribed BL/BLI combinations. Cefiderocol demonstrated *in vitro* activity against *P. aeruginosa*, showing high susceptibility across the different breakpoint interpretive criteria (CLSI 99.5%, EUCAST 98.9%, FDA 97.9%).² Susceptibility to cefiderocol remained consistently high among highly resistant subsets, including BL/BLI-non-susceptible isolates (91.4% to 96.0% susceptible by CLSI criteria) and isolates harboring the VIM (Verona integron-encoded metallo-beta-lactamase), NDM (New Delhi metallo-beta-lactamase), and IMP (imipenemase) enzymes, whereas BL/BLI combinations generally exhibited low susceptibility (30.4% to 41.8% susceptible by CLSI criteria).²

These findings add to a growing body of evidence supporting the use of cefiderocol as a treatment for VAP caused by *P. aeruginosa**, particularly in settings where resistance to BL/BLI combinations may limit treatment options, including infections caused by difficult-to-treat MBL-producing strains.² Cefiderocol maintained high susceptibility against a contemporary global collection of *P. aeruginosa* VAP isolates, including highly resistant phenotypes where cross-resistance among commonly used comparator BL/BLI agents was observed.²

"As resistance among *P. aeruginosa* isolates continues to increase, clinicians need treatment options that retain activity against difficult-to-treat Gram-negative pathogens," said Christine Slover, Vice President, Medical Affairs, Shionogi Inc. "This analysis provides contemporary insight into susceptibility trends among isolates from patients with ventilator-associated pneumonia, including evidence of cross-resistance across commonly used beta-lactam/beta-lactamase inhibitor combinations. Findings such as these help inform our understanding of the evolving resistance landscape and activity against difficult-to-treat pathogens."

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

New Systematic Literature Review Highlights the Body of Evidence Supporting Cefiderocol for the Treatment of Infections Caused by *S. maltophilia*

Shionogi will also present findings from a systematic literature review of 45 published case reports and cohort studies examining clinical outcomes associated with cefiderocol for the treatment of infections caused by *S. maltophilia*, an opportunistic Gram-negative bacterium intrinsically resistant to many antibiotics and associated with significant morbidity and mortality in severely ill and immunosuppressed patients with limited treatment options.^{3,7-9}

Results showed a clinical response in 71.4% of patients described in case reports (35/49), with favorable microbiological and clinical outcomes reported across a range of invasive *S. maltophilia* infections.³ These findings add to the published clinical evidence for cefiderocol in *S. maltophilia* infections. The [2026 AMR Guidance](#) lists cefiderocol as the preferred treatment for invasive *S. maltophilia* infections, noting that this preference is based largely on animal model data, as clinical outcomes data remain limited.¹⁰

About Shionogi in Infectious Disease

For more than 60 years, Shionogi has discovered and commercialized 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- and middle-income countries and select high-income countries.

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 Shionogi Inc.

Shionogi Inc. is a U.S. subsidiary of Shionogi & Co., Ltd., a global research-driven pharmaceutical company. Since 1878, Shionogi has been developing new treatments to improve patients' lives worldwide. Today in North America, our portfolio of FDA approved products includes an antibiotic for serious infections caused by susceptible Gram-negative bacteria, an oral antiviral for post-exposure prophylaxis of COVID-19 and a therapy for amyotrophic lateral sclerosis (ALS). Our pipeline programs include investigational treatments across infectious disease, rare disease and additional high-need therapeutic areas. Together with our subsidiaries Qpex Biopharma Inc. and Shionogi Canada Inc., we are continuing to innovate for patients in the U.S. and worldwide. Learn more at shionogi.com.

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 and CNS disorders. Shionogi's research and development currently targets two therapeutic areas: infectious

diseases and diseases with unmet medical needs, including rare diseases, allergy/inflammation, oncology, hearing loss, and sleep apnea. For more information on Shionogi & Co., Ltd., please visit <https://www.shionogi.com/global/en>.

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.

For Further Information:

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

U.S. Media: ShionogiCommunications@shionogi.com

Shionogi Europe Press Office: pressoffice@shionogi.eu

References

- ¹ Carr A, et al. Outcomes of Cefiderocol Treatment in US Patients with Respiratory Tract Infections: Subgroup Analysis of the PROVE Observational Study. Poster presented at IDWeek 2026. Poster #144.
- ² Nguyen ST, et al. SENTRY Poster Cefiderocol Activity Across Highly Resistant Pseudomonas aeruginosa Ventilator-Associated Pneumonia Isolates: A Global Surveillance Study of SENTRY 2020–2024. Poster presented at IDWeek 2026. Poster #459.
- ³ Martin A, et al. Systematic Literature Review of the Clinical Outcomes Associated with Cefiderocol Therapy for Stenotrophomonas maltophilia Infections. Poster presented at IDWeek 2026. Poster #94.
- ⁴ Fetroja® Prescribing Information. Available from: <https://www.shionogi.com/content/dam/shionogi/si/products/pdf/fetroja.pdf>. Accessed October 7, 2026.
- ⁵ Clancy CJ, Cornely OA, Marcella SW, et al. Effectiveness and safety of cefiderocol in clinical practice for treatment of patients with Gram-negative bacterial infections: US interim results of the PROVE study. *Infection and Drug Resistance*. 2024 Dec 31:4427–43. doi: [10.2147/IDR.S475462](https://doi.org/10.2147/IDR.S475462)
- ⁶ JMI Laboratories [Internet]. SENTRY Antimicrobial Surveillance Program. Available from: <https://www.jmilabs.com/sentry-surveillance-program/>. Accessed October 7, 2026.
- ⁷ Chen L, et al. Assessment of the relative benefits of monotherapy and combination therapy approaches to the treatment of hospital-acquired Stenotrophomonas maltophilia pneumonia: a multicenter, observational, real-world study. *Ann Intensive Care*. 2023;13:47. doi: [10.1186/s13613-023-01144-7](https://doi.org/10.1186/s13613-023-01144-7)
- ⁸ Puech B, et al. Effect of antibiotic therapy on the prognosis of ventilator-associated pneumonia caused by Stenotrophomonas maltophilia. *Ann Intensive Care*. 2021;11(1):160. doi: [10.1186/s13613-021-00950-1](https://doi.org/10.1186/s13613-021-00950-1)

⁹ Mojica MF, et al. Treatment approaches for severe *Stenotrophomonas maltophilia* infections. *Curr Opin Infect Dis*. 2023;36(6):572–584. doi: [10.1097/QCO.0000000000000975](https://doi.org/10.1097/QCO.0000000000000975)

¹⁰ Infectious Disease Society of America [Internet]. IDSA 2026 Guidance on the Treatment of Antimicrobial Resistant Gram-Negative Infections. Available from: <https://www.idsociety.org/practice-guideline/amr-guidance/>. Accessed October 7, 2026.