PRESSRELEASE

SHIONOGI

FDA Accepts Shionogi's sNDA for Fetroja® (cefiderocol) for Use in Pediatric Patients with Serious Infections Caused by Susceptible Gram-negative Bacteria

Submission intends to address a critical therapeutic gap
for vulnerable young patients facing drug-resistant pathogens

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OSAKA, Japan, July 17, 2026 –Shionogi & Co., Ltd., (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, PhD; hereinafter "Shionogi") announced the U.S. Food and Drug Administration (FDA) has accepted a Supplemental New Drug Application (sNDA) for Fetroja® (cefiderocol) for the treatment of pediatric patients (at least 26 weeks of gestational age) with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) and complicated urinary tract infections (cUTI), including pyelonephritis, caused by certain Gram-negative microorganisms.

The FDA has set an action date of February 23, 2027 under the Prescription Drug User Fee Act (PDUFA). The sNDA was submitted by Shionogi Inc., the U.S. subsidiary of Shionogi & Co., Ltd., and is supported by results from three clinical studies that investigated the safety, tolerability and pharmacokinetics and efficacy of cefiderocol in 154 children from birth (at least 26 weeks of gestational age) to less than 18 years of age, with cUTI, HABP/VABP and other infections caused by suspected or confirmed Gram-negative bacteria.[1,2,3]

In 2023, cefiderocol was included in the World Health Organization's PAediatric Drug Optimization (PADO) priority list, which identifies medicines most urgently needed for children, especially where there are gaps in dosing, safety data, or age-appropriate formulations.[4]

The expansion of Fetroja for pediatric HABP/VABP is supported by an ongoing contract with the U.S. Government through the Biomedical Advanced Research and Development Authority's (BARDA) Project BioShield. This project has been funded with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50126C00004.

Fetroja is approved in the U.S. for the treatment of adult patients with cUTIs, including pyelonephritis and HABP/VABP caused by suspected or confirmed Gram-negative bacterial infections.[5] For full Prescribing Information for Fetroja, including approved indications and Safety Information, please visit https://www.shionogi.com/content/dam/shionogi/si/products/pdf/fetroja.pdf.

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 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 most low-, lower middle- and upper middle-income countries, and select high-income countries.

Shionogi ranked second 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.

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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[1] Clinical Trials.gov [Internet]. A Study to Assess the Safety, Tolerability, and Pharmacokinetics of Cefiderocol in Hospitalized Pediatric Participants. Available from: https://clinicaltrials.gov/study/NCT04215991

[2] Clinical Trials.gov [Internet]. A Study to Assess the Safety, Tolerability, and Pharmacokinetics of Single and Multiple Doses of Cefiderocol in Hospitalized Pediatric Participants. Available from: https://clinicaltrials.gov/study/NCT04335539

[3] Clinical Trials.gov [Internet]. A Study to Assess the Safety, Tolerability, and Pharmacokinetics of Cefiderocol in Hospitalized Neonates and Infants. Available from: https://clinicaltrials.gov/study/NCT06086626

[4] World Health Organization [Internet]. Towards investigation, development and introduction of cefiderocol in children: product brief. Available from: https://www.who.int/publications/i/item/9789240084599

[5] Fetroja® Prescribing information. Available from: https://www.shionogi.com/content/dam/shionogi/si/products/pdf/fetroja.pdf. Accessed June 2026.