PRESSRELEASE

SHIONOGI

Shionogi Receives Contract with U.S. Government Through BARDA's Project BioShield to Enhance National Preparedness for Drug-Resistant Bacterial Threats

Program Includes Establishing Pharmaceutical Manufacturing in the U.S., Procurement and Development of Treatment for Infections Caused by Biothreat Pathogens

OSAKA, Japan, April 8, 2026 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Shionogi Inc., a New Jersey-based subsidiary of Shionogi, has been awarded a contract through the Biomedical Advanced Research and Development Authority's (BARDA) Project BioShield related to Fetroja® (cefiderocol) as a critical countermeasure against difficult-to-treat Gram-negative bacterial infections and pathogens that present a high-priority biothreat to national health security. The contract is initially funded at $119 million with multiyear options for a total of up to $482 million.

The contract will bolster the U.S. government's ability to respond to national health security threats and strengthen domestic manufacturing capabilities and supply readiness by funding Shionogi Inc. to:

- Establish a U.S. drug product manufacturing site for Fetroja.
- Support procurement of Fetroja.
- Advance Fetroja for the treatment of infections caused by high priority biothreat pathogens, including *Burkholderia pseudomallei* (melioidosis) and *Yersinia pestis* (plague).
- Expand the utility of Fetroja for HABP/VABP in pediatric patients with a U.S. Food and Drug Administration (FDA) Supplemental New Drug Application (sNDA).

"Since the 1950s, Shionogi has been researching, developing and partnering to deliver innovative antibiotics to patients worldwide," said John Keller, Ph.D., Director of the Board, Senior Vice President, R&D Supervisory Unit, Shionogi. "Fetroja, the world's first siderophore cephalosporin antibiotic, is a prime example of our in-house innovation and this contract is a continuation of the way we collaborate with global government and non-governmental organizations to drive innovation."

"Shionogi is proud of our ongoing commitment to combating antimicrobial resistance, as shown by the continued investment in Fetroja since its introduction in 2020, expanding our portfolio with the acquisition of Qpex Biopharma, Inc. in 2023, and further investing in Qpex to establish a new research facility dedicated to advancing antimicrobial research and development in 2025," said Nathan McCutcheon, MBA, President and CEO, Shionogi Inc. "This contract complements our existing work with the U.S. government and enables us to advance our ongoing expansion efforts in the U.S. at greater pace and scale."

This project has been funded with Federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50126C00004.

BARDA's Project BioShield accelerates the research, development, procurement and availability of effective medical countermeasures against chemical, biological, radiological and nuclear (CBRN) agents.

In the U.S. Fetroja is approved by the FDA for the treatment of hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), and complicated urinary tract infections caused by certain susceptible Gram-negative microorganisms. In Japan cefiderocol is commercially available under the brand name Fetroja® for various infections caused by strains resistant to carbapenem antibiotics. 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. See Fetroja U.S. full indications and important safety information below in the About Cefiderocol section.

For Full U.S. Prescribing Information for Fetroja® (cefiderocol), including approved indications and safety information, please visit Fetroja Prescribing Information.

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 include 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 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 targets 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 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. 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. 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*.

U.S. INDICATIONS
Fetroja® (cefiderocol) is indicated in patients 18 years of age or older for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa,* and *Enterobacter cloacae* complex.

Fetroja is indicated in patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms: *Acinetobacter baumannii* complex*, Escherichia coli, Enterobacter cloacae* complex*, Klebsiella pneumoniae, Pseudomonas aeruginosa,* and *Serratia marcescens*.

USAGE
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Fetroja and other antibacterial drugs, Fetroja should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
Fetroja is contraindicated in patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of Fetroja.

WARNINGS AND PRECAUTIONS
Increase in All-Cause Mortality in Patients with Carbapenem-Resistant Gram-Negative Bacterial Infections
An increase in 28-day all-cause mortality was observed in Fetroja-treated nosocomial pneumonia, bloodstream infections, or sepsis patients compared to those treated with best available therapy (BAT) in a clinical study (NCT02714595). Most BAT regimens contained colistin. All-cause mortality remained higher in patients treated with Fetroja than in patients treated with BAT through Day 49.

Generally, deaths were in patients with infections caused by Gram-negative organisms, including non-fermenters such as *Acinetobacter baumannii* complex, *Stenotrophomonas maltophilia*, and *Pseudomonas aeruginosa*, and were the result of worsening or complications of infection, or underlying comorbidities.

The cause of the increase in mortality has not been established. Closely monitor the clinical response to therapy in patients with cUTI and HABP/VABP.

Hypersensitivity Reactions
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Hypersensitivity was observed with Fetroja. Before Fetroja is instituted, inquire about previous hypersensitivity to cephalosporins, penicillins, or other beta-lactam drugs. If an allergic reaction occurs, discontinue Fetroja.

***Clostridioides difficile*-associated Diarrhea (CDAD)**
CDAD has been reported with nearly all systemic antibacterial agents, including Fetroja. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterial drugs not directed against *C. difficile* may need to be discontinued.

Seizures and Other Central Nervous System (CNS) Adverse Reactions
Cephalosporins, including Fetroja, have been implicated in triggering CNS adverse reactions such as seizures. Encephalopathy, coma, asterixis, and neuromuscular excitability have been reported with cephalosporins, particularly in patients with a history of epilepsy and/or when recommended dosages of cephalosporins were exceeded due to renal impairment. Adjust Fetroja dosing based on creatinine clearance. If focal tremors or seizures occur, evaluate patients to determine whether Fetroja should be discontinued.

Development of Drug-Resistant Bacteria
Prescribing Fetroja in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS
The most common adverse reactions occurring in ≥2% of patients receiving Fetroja in the cUTI trial were: diarrhea (4%), infusion site reactions (4%), constipation (3%), rash (3%), candidiasis (2%), cough (2%), elevations in liver tests (2%), headache (2%), hypokalemia (2%), nausea (2%), and vomiting (2%). The most common adverse reactions occurring in ≥4% of patients receiving Fetroja in the HABP/VABP trial were: elevations in liver tests (16%), hypokalemia (11%), diarrhea (9%), hypomagnesemia (5%), and atrial fibrillation (5%).

Please click here for Full U.S. Prescribing Information for Fetroja® (cefiderocol).

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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