

Submission of Letter of Intent and Concept Note to the Kenyan Ministry of Health to Accelerate Access to Cefiderocol

July 18, 2025 –Shionogi & Co., Ltd. (Head Office: Chuo-ku, Osaka, Japan; hereinafter, "Shionogi"), in collaboration with the Global Antibiotic Research & Development Partnership (Head Office: Geneva, Switzerland; hereinafter "GARDP"), has agreed to collaborate with the Ministry of Health of the Republic of Kenya (hereinafter, "Kenya") on a project aiming to facilitate the introduction of cefiderocol, a treatment for serious Gram-negative bacterial infections in adults with limited treatment options, in the country. Shionogi and GARDP submitted to the Kenyan Ministry of Health a Letter of Intent and a project Concept Note, which were subsequently accepted.

The project proposes to support the appropriate use of cefiderocol in select tertiary hospitals through a phased approach that aligns with the Kenyan Ministry of Health antimicrobial stewardship framework and national AMR priorities. This project will be a collaborative effort between Shionogi, GARDP, the Kenyan Ministry of Health, and other Kenyan stakeholders, and it will generate critical insights to inform broader access strategies for Kenya and beyond.

One of Shionogi's key material issues is to "Improve Access to Healthcare". Shionogi is committed to strengthening collaborative initiatives with domestic and international partners, contributing to the development of a sustainable society.^{1,2} These efforts include improving access to antimicrobial treatments* and supporting maternal and child health programs in Africa.** As a global leader in infectious disease treatment, Shionogi continues to actively address a wide range of public health challenges, including some of the world's major infectious diseases, such as AMR and COVID-19.

*For more information on Shionogi's initiatives on AMR, please click [<u>here</u>]. **For more information on Shionogi's maternal and child health initiatives in Africa, please click [<u>here</u>].

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.³ 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.⁴ 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.⁵*

About Antimicrobial Resistance:

Antimicrobial resistance (AMR), the phenomenon where bacteria acquire resistance to antibiotics, is one of the most significant global public health threats facing humanity and requires urgent action. AMR has been referred to as a "silent pandemic," and without countermeasures, it is projected to result in over 1.91 million deaths annually by 2050.⁶

Reference:

- 1. <u>Shionogi, GARDP and CHAI announce landmark license and collaboration agreements to treat bacterial</u> infections by expanding access to cefiderocol in 135 countries | News | Shionogi Co., Ltd.
- 2. <u>Shionogi, Nagasaki University, Saraya, and Connect Afya Enter into a Comprehensive Partnership</u> <u>Agreement to Support Antimicrobial Stewardship in Kenya</u> <u>SHIONOGI</u>
- 3. Fetcroja® Summary of Product Characteristics. Available at: Fetcroja, INN-cefiderocol
- Fetroja® Prescribing information. Available at: <u>https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209445s000lbl.pdf</u>
- 5. <u>Press release on November 30, 2023.</u> Regarding the Acquisition of Manufacturing and Marketing Approval for the New Siderophore Cephalosporin Antibiotic Fetroja[®](cefiderocol) Intravenous Infusion 1g vial in
- 6. GBD 2021 Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050. Lancet. 2024 Sep 28;404(10459):1199–1226. doi:10.1016/S0140-6736(24)01867-1. Epub 2024 Sep 16.

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, Contact:

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