PRESSRELEASE

SHIONOGI

Domestic Launch of the In Vitro Diagnostic Pharmaceutical "Shionogi MIC Dry Plate Cefiderocol"

OSAKA, Japan, July 8, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereinafter, "Shionogi") announced the launch of the in vitro diagnostic product "Shionogi MIC Dry Plate Cefiderocol" to measure sensitivity to the gram-negative bacterial-infection treatment Fetroja® (generic name: Cefiderocol; hereinafter "Fetroja") on July 8, 2024.

In the context of addressing antimicrobial resistance (AMR), measuring the susceptibility of bacteria, suspected to cause infections, to various drugs, and identifying the causative bacteria to use appropriate antibiotics is crucial to prevent the emergence of new resistant strains. This enhancement in the drug-sensitivity testing system is expected to contribute to the more appropriate use of Fetroja.

Shionogi has identified "protecting people from the threat of infectious diseases" as a material issue, and is committed to realizing total care for patients with infectious diseases. We will continue our efforts to deliver necessary antimicrobial treatments to patients worldwide as quickly as possible, in order to address the global challenge of AMR. Moreover, we will promote the appropriate use of antibiotics, thereby contributing to the treatment of patients with AMR infections and preparing for future threats.

*MIC (Minimum Inhibitory Concentration): The lowest concentration of a drug that prevents bacterial growth. Lower MIC values indicate higher efficacy of the antibiotic.

About cefiderocol (Fetroja®)

Cefiderocol for injection is the first and only siderophore cephalosporin antibiotic for the treatment of serious Gram-negative infections. It has a novel mechanism for penetrating the outer cell membrane of Gram-negative pathogens by acting as a siderophore. In addition to entering cells by passive diffusion through porin channels, cefiderocol binds to ferric iron and is actively transported into bacterial cells through the outer membrane via the bacterial iron transporters, which function to incorporate this essential nutrient for bacteria. These mechanisms allow cefiderocol to achieve high concentrations in the periplasmic space where it can bind to penicillin-binding proteins and inhibit cell wall synthesis in the bacterial cells. Cefiderocol has obtained approval in Japan, Taiwan, Europe, and the United States, and is marketed under the brand name "Fetroja®" in Japan, Taiwan, and the United States, and "Fetcroja®" in Europe. Fetroja is also listed on the WHO Essential Medicines List. Furthermore, to improve access for patients in many low- and middle-income countries as well as high- and middle-income countries, preparations are underway through a tripartite agreement with The Global Antibiotic Research and Development Partnership (GARDP) and the Clinton Health Access Initiative (CHAI).[1]

About Antimicrobial resistance (AMR)

Antimicrobial resistance (AMR) refers to the phenomenon where bacteria acquire resistance to antimicrobial drugs, rendering these medications less effective. Often termed the "silent pandemic," AMR is one of the global public health threats humanity faces today, demanding urgent worldwide action[2,3]. In 2019, it was estimated that AMR caused the deaths of 1.27 million people globally[4]. Furthermore, without international cooperation and effective measures, AMR could result in over 10 million deaths annually by 2050, with an estimated cumulative impact of $100 trillion on the global economy[5].

Click here to learn more about our efforts to address the threat of AMR infections.

Reference:

1. Shionogi, GARDP and CHAI announce landmark license and collaboration agreements to treat bacterial infections by expanding access to cefiderocol in 135 countries | News | Shionogi Co., Ltd.
2. Antimicrobial resistance (who.int)
   WHO. Antimicrobial resistance. Who.int. Published October 13, 2020.
3. WHO Bacterial Priority Pathogens List, 2024. Accessed May 24, 2024. Available at: https://iris.who.int/bitstream/handle/10665/376776/9789240093461-eng.pdf?sequence=1
4. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet 2022; 399: 629–55
5. 160525_Final paper_with cover.pdf (amr-review.org)
   O'Neill J. 'Tackling Drug-Resistant Infections Globally: Final Report and Recommendations'. Review on Antimicrobial Resistance. May 2016.

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