PRESSRELEASE

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Shionogi & Co., Ltd.
Shionogi Pharma Co., Ltd

Shionogi Pharma's Kanegasaki Plant Receives "BSI Kitemark™ for Minimized Risk of AMR" Certification for Antimicrobial Manufacturing

- First certification in Japan for an antibacterial manufacturing facility
- World's second certification covering both API and formulation manufacturing processes for a specific product within a single site

OSAKA, Japan, November 4, 2025 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") and its group company Shionogi Pharma Co., Ltd. (Head Office: Osaka; Japan, Representative Director and President: Yasunori Isou; hereinafter "Shionogi Pharma") today announced that Shionogi Pharma's Kanegasaki Plant (Iwate Prefecture, Japan) has obtained the international certification "BSI Kitemark™ for Minimized Risk of AMR" for both the active pharmaceutical ingredient (API) and formulation manufacturing processes of cefiderocol, a treatment for infections caused by multidrug-resistant Gram-negative bacteria.

The BSI Kitemark™ for Minimized Risk of AMR certification ("the Certification") was established in 2023 by the British Standards Institution (BSI) to promote responsible antibiotic manufacturing across global supply chains. This certification verifies that antibacterial manufacturing processes are appropriately managed in accordance with international standards designed to minimize the release of harmful substances into aquatic environments and to prevent the spread of antimicrobial resistance (AMR). The certification is granted for specific combinations of product, manufacturing facility, and manufacturing process (API or formulation). This certification is currently granted to approximately 90 units worldwide.

The Kanegasaki Plant, one of Japan's leading integrated sites for antibacterial manufacturing—from API production to formulation—has built a rigorous management system to minimize and control environmental emissions of antibacterials. With this certification, the plant's compliance with international standards and its commitment to minimizing environmental impact in the manufacturing of cefiderocol have been independently verified by a third party. This represents the first certification in Japan for an antibacterial manufacturing facility and the second case worldwide where both API and formulation processes for a specific product have been certified within a single site.

As part of its sustainability management, the SHIONOGI Group has identified "Protect people from the threat of infectious diseases" as a key material issue, and is committed to achieving total care for infectious diseases. The acquisition of this certification marks an important milestone toward sustainable growth in partnership with society and the creation of a better future. Going forward, the SHIONOGI Group will not only expand certification efforts within its own facilities but also promote the adoption of this standard across its domestic and global antibacterial supply chains, contributing proactively to the realization of a society with a minimized risk of AMR.

About Cefiderocol

Cefiderocol has been approved in the U.S., Europe, Taiwan, and Japan, where it is marketed under the brand names FETROJA® (U.S., Japan and Taiwan), and FETCROJA®. To improve patient access to cefiderocol in low- and middle-income countries, Shionogi is working with the Global Antibiotic Research and Development Partnership (GARDP) and the Clinton Health Access Initiative (CHAI) under a three-party collaboration agreement[1]

About Antimicrobial Resistance（AMR）

AMR is a major health burden that urgently needs to be addressed. Globally, in 2021, there were 1.14 million deaths attributable to bacterial AMR.[2] Infections caused by carbapenem-resistant Gram-negative bacteria are often associated with a high mortality rate.[3] If no action is taken, drug-resistant pathogens could cause more than 39 million deaths over the next 25 years.[4]

For more information on Shionogi's efforts to address AMR, please visit Address the problem of antimicrobial resistance (AMR) .

About the British Standards Institution (BSI)

The British Standards Institution (BSI) is a business improvement and standards company that partners with more than 77,500 clients globally across multiple industry sectors. BSI provides organizations with the confidence to grow by working with them to tackle society's critical issues – from climate change to building trust in AI and everything in between - to accelerate progress towards a fair society and a sustainable world.

For over a century BSI has been recognized for having a positive impact on organizations and society, building trust and enhancing lives. Today BSI engages with a 15,000 strong global community of experts, industry and consumer groups, organizations and governments to deliver on its purpose by helping its clients fulfil theirs.

References:

1. June 15, 2022 Press Release：Shionogi, GARDP and CHAI announce landmark license and collaboration agreements to treat bacterial infections by expanding access to cefiderocol in 135 countries
2. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet 2022; 399: 629–55.
3. 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. PMID: 39299261.
4. Antimicrobial resistance (who.int) WHO. Antimicrobial resistance. Who.int. Published October 13, 2020. https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance

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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