PRESSRELEASE

SHIONOGI

Approval for Cefiderocol in China

OSAKA, Japan, January 8, 2026 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that its group company, Shionogi China Co., Ltd. (Head Office: Shanghai, China; Chairman: Hirofumi Nagatome), has received approval from the National Medical Products Administration (NMPA) of China for cefiderocol (generic name: Cefiderocol Sulfate Tosylate for Injection; hereinafter "cefiderocol") for the treatment of complicated urinary tract infections including pyelonephritis caused by Gram-negative bacteria.

This approval is based on positive results from an international multicenter clinical study[1] and a randomized, double-blind, multicenter study[2] conducted in China. In both studies, which aimed to verify non-inferiority to the comparator drug, cefiderocol demonstrated non-inferiority to imipenem/cilastatin and achieved the primary endpoint. Furthermore, no new safety concerns were identified, and cefiderocol was well tolerated.

Antimicrobial resistance (AMR) occurs when bacteria develop resistance to antibiotics, making infections harder to treat. AMR is often referred to as a "silent pandemic" and is recognized as one of the most pressing global public health threats requiring urgent action[3]. In 2021, AMR was estimated to have caused 1.14 million deaths worldwide[4]. Without coordinated international efforts, it is projected that more than 39 million lives could be lost over the next 25 years[5]. Meanwhile, treatment options remain limited, making this an area of high unmet medical need. With this approval, cefiderocol is expected to provide a new treatment option for patients in mainland China suffering from difficult-to-treat complicated urinary tract infections.

Shionogi has identified "Protecting people from the threat of infectious diseases" as a material issue and is committed to realizing total care for infectious diseases. We will continue to work toward delivering essential anti-infective treatments to patients worldwide as quickly as possible, contributing to global efforts to combat AMR. For more information on Shionogi's initiatives against AMR, please visit.

Clich here to learn more about our efforts to address antimicrobial resistance.

About Cefiderocol

Cefiderocol is an antibiotic that penetrates the outer membrane of Gram-negative bacteria, including multidrug-resistant strains, to exert its antibacterial activity. As of December 2025, cefiderocol is marketed in 27 countries and regions, including Japan, Europe, U.S., Taiwan and China. It is listed on the WHO Model List of Essential Medicines, demonstrating its continued importance in improving outcomes for patients with some of the most difficult-to-treat Gram-negative infections. Prior to this approval, the Hainan Provincial Medical Products Administration had authorized its clinical use in the Boao Lecheng International Medical Tourism Pilot Zone in China[6].

References

1. Press release: January 12, 2017
2. Chinese Clinical Trial Registry: Phase III clinical trial registration number CTR20223300
3. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet 2022; 399: 629–55.
4. 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.
5. Antimicrobial resistance (who.int) WHO. Antimicrobial resistance. Who.int. Published October 13, 2020.
6. Press release: August 5, 2024

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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