



## **Cefiderocol is approved for clinical use in Boao Lecheng International Medical Tourism Pilot Zone, Hainan, China**

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**OSAKA, Japan, January 31, 2024** - Shionogi & Co. Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Ping An-Shionogi Co., Ltd. (Head Office: Shanghai, China; Chairman and CEO: Tatsumori Yoshida, hereafter "Ping An-Shionogi ") has received approval from the Hainan Medical Products Administration for the clinical use of cefiderocol, a new siderophore cephalosporin antibiotic, in Boao Lecheng International Medical Tourism Pilot Zone, Hainan, China.

The current approval is based on the application from Hainan Ruijin Hospital (Boao Research Hospital) Affiliated to Shanghai Jiao Tong University School of Medicine. Cefiderocol is a medication that effectively penetrates the outer membrane of gram-negative bacteria, including multidrug-resistant bacteria, and exhibits antimicrobial activity. Cefiderocol is sold under the product name Fetcroja® in Europe and Fetcroja® in the United States and Japan, and has contributed to the treatment of patients suffering from infections caused by drug-resistant bacteria. In China, Ping An-Shionogi is currently conducting Phase III clinical trials for the regular approval application of cefiderocol. But with the current approval, cefiderocol can be used for patients in Hainan Boao Lecheng International Medical Tourism Pilot Zone, prior to obtaining regular approval in mainland China.

Antimicrobial resistance (AMR) or the acquisition of bacterial resistance to antibiotics, is a global public health threat that humanity faces, and it is an urgent and important issue that needs to be addressed on a global scale<sup>1</sup>. In China, it is estimated that there were 145,500 deaths attributable to AMR and 602,600 deaths associated with AMR in 2019<sup>2</sup>. Those numbers are considered to have been increasing at present.

Shionogi has identified "Protect people from the threat of infectious diseases" as a material issue (materiality) to address, and is working towards achieving comprehensive care for infectious diseases. We are committed to protecting the health of people by delivering the necessary infectious disease treatments to patients around the world as quickly as possible, in order to contribute to the successful management of global challenges such as COVID-19 and AMR.

[Click here](#) to learn more about our efforts to address drug resistance.

## **About Boao Lecheng International Medical Tourism Pilot Zone**

The Hainan Boao Lecheng International Medical Tourism Pilot Zone (" Boao Lecheng ") is located on both sides of the Wanquan River near Qionghai city at the island of Hainan Province. The Boao Lecheng Pilot Zone is granted specific policies entailing that FDA licensed pharmaceuticals or CE marked medical devices may be used in the Pilot Zone after a relatively short procedure. Boao Lecheng cooperates closely with the multinational pharmaceutical and medical device companies in the world. Until so far more than 300 pharmaceutical products and medical devices have been introduced in Boao Lecheng.

## **About Cefiderocol**

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 already obtained approval in Europe, United States and Japan and is sold under the product name Fetcroja® in Europe and Fetroja® in the United States and Japan<sup>3</sup>. It is listed on the World Health Organization's Essential Medicines List, and preparations are underway through a collaborative agreement with The Global Antibiotic Research and Development Partnership (GARDP) and Clinton Health Access Initiative (CHAI) to improve access to this new antibacterial agent for patients in many low- and middle-income countries and high- and middle-income countries<sup>4</sup>.

## **References**

1. WHO. Antimicrobial resistance. Who.int. Published October 13, 2020. <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>
2. [Global Health Data Exchange \(GHDx\), The burden of antimicrobial resistance \(AMR\) in China. The Institute for Health Metrics and Evaluation, Washington University](#)
3. [Press release on November 30, 2023](#)  
Regarding the Acquisition of Manufacturing and Marketing Approval for the New Siderophore Cephalosporin Antibiotic Fetroja® (cefiderocol) Intravenous Infusion 1g vial in Japan
4. [Press release on June 15, 2022](#)  
Shionogi, GARDP and CHAI announce landmark license and collaboration agreements to treat bacterial infections by expanding access to cefiderocol in 135 countries

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