

GARDP, CHAI and Shionogi announce MOU to increase access to antibiotic to treat antimicrobial resistant infections in low- and middle-income countries



July 13, 2021 – The Global Antibiotic Research and Development Partnership (GARDP), the Clinton Health Access Initiative (CHAI) and Shionogi & Co., Ltd today announced a Memorandum of Understanding (MOU) to accelerate access, including in low- and middle-income countries, to the antibiotic cefiderocol for bacterial infections in patients with limited treatment options.

Cefiderocol, a siderophore cephalosporin, uses a novel “Trojan horse” mechanism to enable penetration of Gram-negative bacteria and is a potential treatment option for some antibiotic-resistant infections. Cefiderocol, first approved in 2019, is active against many types of Gram-negative bacteria and is approved for use in the United States and the European Union.

Through this MOU, GARDP, CHAI and Shionogi will use their collective expertise to increase access to cefiderocol in low- and middle-income countries. Together, the collaboration will aim to assist governments and partners to introduce cefiderocol into health systems, with a focus on providing clinical guidance to physicians, training and other measures to ensure appropriate use.

Antimicrobial resistance (AMR) occurs when bacteria, viruses, fungi or parasites no longer respond to medicines, making infections from resistant organisms difficult or impossible to treat. Bacteria of concern, such as *E. coli*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae* and *Acinetobacter baumannii*, can cause a variety of serious infections, including pneumonia, urinary tract infections, bloodstream infections and sepsis, and are often resistant to most available antibiotics. Cefiderocol could be a valuable tool to treat such resistant infections. Prescribing information, including indications and usage, warnings and precautions is available on the U.S. Food and Drug Administration and European Medicines Agency labels.

AMR is a growing public health threat globally, leading to more than 700,000 deaths each year. The World Health Organization (WHO) has identified antimicrobial resistance as a leading risk to health and economic development and a barrier to reaching sustainable development goals.¹ This year, G7 Health Ministers committed to making AMR a key strategic area for action.² Unlike COVID-19, which raised alarm as it swiftly moved across the globe, AMR is a silent pandemic that has gained ground in countries and hospitals with little public notice.³

“Antibiotic-resistant infections aren’t just a statistic. They represent lives upended, irrevocably changed and all too often lost,” said Dr. Subasree Srinivasan, Medical Director, GARDP. “Antibiotic-resistant bacteria can infect anyone, of any age, anywhere, but it is the most vulnerable who are hit first and hardest. This collaboration with CHAI and Shionogi aims to improve our ability to reach vulnerable people, including in low- and middle-income countries, with an antibiotic for serious infections with

¹ <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>

² <https://www.who.int/news/item/09-06-2021-record-response-to-who-s-call-for-antimicrobial-resistance-surveillance-reports-in-2020>

³ <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>

limited treatment options, and to ensure its use is governed by principles of appropriate and sustainable access.”

“We are committed to the fight against infectious diseases and AMR,” stated Ms. Takuko Sawada, Director of the Board, Executive Vice President, Shionogi & Co., Ltd. “AMR currently kills 700,000 people worldwide and there is a need for new treatment options. In addition to improving access, it is important to address environment health challenges, improve diagnosis and secure appropriate use. GARDP and CHAI have tremendous local knowledge and infrastructure which will be critical to help address AMR on a global basis. We believe that this initiative will make a significant contribution to resolving this difficult problem.”

While the risk from AMR infections continues to increase, only a small number of new antibiotics have been developed in recent years. Barriers to access, including lack of awareness of novel treatments and their applicability in specific settings, economic and regulatory challenges or medication shortages, can impact use in countries at all levels of development. However, these challenges are particularly acute in low- and middle-income countries.

“We are excited to collaborate with GARDP and Shionogi to help increase access to this antibiotic in low- and middle-income countries,” stated Dr. David Ripin, Chief Science Officer and Executive Vice President Infectious Diseases, Clinton Health Access Initiative. “Through this initiative we have the chance to combat the silent pandemic of antimicrobial resistance and ensure access to the newest treatments for patients regardless of where they live.”

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About the partners

GARDP | The Global Antibiotic Research and Development Partnership (GARDP) is a Swiss not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. GARDP was created by the World Health Organization (WHO) and the Drugs for Neglected Diseases *initiative* (DNDi) in 2016 to ensure that everyone who needs antibiotics receives effective and affordable treatment. We aim to develop five new treatments by 2025 to fight drug-resistant infections. GARDP is funded by the governments of Germany, Japan, Luxembourg, Monaco, Netherlands, South Africa, Switzerland, United Kingdom, as well as Médecins Sans Frontières and private foundations. GARDP is registered under the legal name GARDP Foundation. www.gardp.org

The Clinton Health Access Initiative | The Clinton Health Access Initiative, Inc. (CHAI) is a global health organisation committed to saving lives and reducing the burden of disease in low-and middle-income countries. We work with our partners to help strengthen the capabilities of governments and the private sector to create and sustain high-quality health systems. For more information, please visit: www.clintonhealthaccess.org.

Shionogi & Co., Ltd. | Shionogi & Co., Ltd. is a 143-year-old global, research driven pharmaceutical company headquartered in Osaka, Japan, that is dedicated to bringing benefits to patients based on its corporate philosophy of “supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” The company currently markets products in several therapeutic areas including anti-infectives, pain, CNS disorders, cardiovascular diseases and gastroenterology. Shionogi’s research and development currently target two therapeutic areas: infectious diseases, and pain/CNS disorders. For more information on Shionogi & Co., Ltd., please visit <https://www.shionogi.com/global/en/>.

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