



Shionogi Expands Global Infectious Disease and Antimicrobial Research Operations to U.S. to Address Current and Emerging Health Threats

- *Expansion Announced at the BIO International Convention with Key Policy and Health Leaders*
- *New U.S. Facility, Established Through Qpex Biopharma, Inc., a Shionogi Group Company, Will Increase Capabilities in Infectious Disease and Pandemic Preparedness*

OSAKA, Japan, June 4, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced the company is responding to the urgent global need for additional antimicrobial research and development by establishing its first discovery laboratory in the U.S., in San Diego, California.

Shionogi made the announcement during a panel discussion at BIO that convened top industry and public health leaders from the White House Office of Pandemic Preparedness and Response Policy; the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS); and the Center for Infectious Disease Research and Policy (CIDRAP).

The Shionogi Qpex Lab will expand the existing R&D facility for Qpex Biopharma, Inc., a Shionogi Group Company (hereafter "Qpex"), with a new state-of-the-art discovery laboratory at the SD Tech by Alexandria mega campus in San Diego.

In 2023, Qpex was [acquired](#) by Shionogi Inc., a New Jersey-based subsidiary of Shionogi. That acquisition brought Qpex's novel internally discovered pipeline, including an investigational beta-lactamase inhibitor, to Shionogi, expanding the company's antimicrobial pipeline and further augmenting its R&D capabilities and expertise. Qpex has an existing contract with BARDA for advancing a portfolio of antibiotics against resistant bacteria.

"It is vital that we invest in the development of new medicines to help mitigate future threats, including pandemics and antimicrobial resistance. In addition, we must lower barriers and create incentives to support the training and development of the next generation of scientists and researchers, particularly in antimicrobial resistance, or AMR, where the workforce has been declining for decades," said Phyllis Arthur, Executive Vice President & Head, Healthcare Policy and Programs, Biotechnology Innovation Organization (BIO), who moderated the panel. "The expertise of Shionogi and Qpex scientists in this facility in the U.S. will enhance drug discovery and development efforts and help make medicines available that can support future public health, economic and national security concerns."

Addressing Unmet Needs in Infectious Disease

As the world becomes more globalized, the risk of pandemic health events increases.¹ A pathogen that can spread quickly has the potential to destabilize economies, compromise national security and lead to millions of deaths.² Infectious diseases have substantial health and economic costs and are becoming difficult to treat. Antimicrobial resistance (AMR) is already responsible for 1.27 million deaths and will cause more than 10 million deaths per year by 2050 without action.^{3,4}

There are hundreds of known bacterial and fungal pathogens, including 24 antibiotic resistant bacteria that are considered priority by the WHO, but the antibiotic R&D pipeline has continued to decline, creating an urgent unmet need to develop new treatments.^{5,6,7,8}

“We need to address known health threats, including antibiotic-resistant bacteria, as well as prepare for rapidly emerging threats that could lead to future pandemics. This is a landmark opportunity to build upon the excellent track record of our organizations in discovering innovative antimicrobial drugs and bringing them to patients,” said Michael N. Dudley, PharmD, President and CEO of Qpex. “Together, with our government and academic partners, we have the capabilities and the capacity to face the known public health crises of today and to prepare for the impact future pathogens may have on society.”

Proven Track Records

Since the 1950s, Shionogi has discovered and introduced novel antibiotics as well as innovative medicines for HIV, influenza, and COVID-19. The Qpex senior leadership team worked together for more than a quarter century and they have completed four regulatory approvals for antibiotics in the past decade.

“Combining the deep expertise of the Qpex team with Shionogi’s decades of successful infectious disease R&D in Japan, this expansion has the potential to accelerate critically needed innovation in infectious disease like never before,” said John Keller, PhD, Senior Executive Officer, Senior Vice President, R&D Supervisory Unit at Shionogi. “In the race between antibiotic drug development and increasing resistance, the pathogens are winning. If new antibiotics are not discovered and developed, we cannot overcome this public health crisis and are at risk of jeopardizing global health security.”

Expanded Capacity for Public-Private Partnerships

Shionogi’s expanded presence in the U.S. will also provide an opportunity to further develop the companies’ partnership network with researchers in both the public and private sectors. The development of the products in Qpex’s portfolio is funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA) under Other Transaction Authority number HHSO100201600026C. Qpex [recently announced](#) additional funding from BARDA to support the advancement of its antibiotic clinical development programs.

Antimicrobial Resistance

AMR is a major health burden that urgently needs to be addressed. Globally, in 2019, there were 1.27 million deaths attributable to bacterial AMR.³ Infections caused by carbapenem-resistant Gram-negative bacteria are often associated with a high mortality rate.⁹ If no action is taken, antimicrobial resistance is predicted to kill 10 million people worldwide every year by 2050, with total expenses to treat AMR infections reaching 412 billion USD annually up to 2035.^{4,10}

Shionogi's Commitment to Fighting Antimicrobial Resistance

Shionogi has a strong heritage in the field of anti-infectives and has been developing antimicrobial therapies for more than 60 years. Shionogi is proud to be one of the few large pharmaceutical companies that continues to focus on research and development in anti-infectives. For more information, please refer to: <https://www.shionogi.com/global/en/sustainability/amr.html>.

About Shionogi & Co. Ltd.

Shionogi & Co., Ltd. is a leading global research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and well-being of the patients we serve." Shionogi has discovered and developed novel antibiotics, medicines for HIV and influenza and currently markets medicines for infectious diseases and central nervous system disorders. Shionogi's global pipeline includes research programs in infectious disease, pain/CNS, metabolic disorders, rare disease, oncology and stroke. For more information, visit <https://www.shionogi.com/global/en/>.

About Qpex Biopharma Inc., a Shionogi Group Company

Qpex Biopharma, Inc. is a resistance-focused infectious disease company on a mission to make both a dramatic and sustainable improvement in patient care across both inpatient and outpatient settings. Advancing a robust portfolio of best-in-class, clinical-stage products, the company's lead program is based on xeruborbactam, an investigational ultra-broad-spectrum beta-lactamase inhibitor discovered by Qpex scientists. For more information, please visit www.qpexbio.com and follow us on [Twitter](#) and [LinkedIn](#).

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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