PRESSRELEASE

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Qpex Biopharma, a Shionogi Group Company, Receives an Additional $10M Award by BARDA as Part of Qpex's Partnership to Advance its Portfolio of Antibiotics Addressing Drug-Resistant Infections

OSAKA, Japan, May 31, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Qpex Biopharma, Inc., a Shionogi Group Company, (hereafter "Qpex") announced the exercise of a $10 million option from the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response at the U.S. Department of Health and Human Services, to support the advancement of the company's antibiotic clinical development program. The option was awarded under the company's existing contract with BARDA that provides up to $132 million in support to advance development of the portfolio of new therapies.

"This award follows the important progress made in our programs since our merger with Shionogi last year," said Michael N. Dudley, Pharm.D., President and CEO of Qpex. "We are grateful for the opportunity to build on our longstanding partnership with BARDA and to continue making progress on our development program as part of a leading global organization with a strong record discovering, developing and commercializing innovative anti-infective products."

The BARDA award will be used to advance xeruborbactam, an investigational beta-lactamase inhibitor, including supporting clinical studies in both IV and oral combinations for infections caused by drug-resistant gram-negative bacteria.

"The urgent, global threat of antimicrobial resistance demands innovation," said John Keller, Ph.D., Senior Executive Officer, Senior Vice President, R&D Supervisory Unit at Shionogi. "Antibiotic drug development is not keeping pace with resistance. Between Qpex's promising pipeline and Shionogi's decades of successful infectious disease R&D, our work has the potential to accelerate critically needed solutions for treating drug-resistant infections worldwide."

According to the Centers for Disease Control (CDC), more than 2.8 million antibiotic-resistant infections arise annually in the U.S.1 Among the most severe and difficult-to-treat infections are caused by drug-resistant gram-negative bacteria, several of which are targeted by the Qpex portfolio.

Qpex was acquired by Shionogi Inc., a U.S. subsidiary of Shionogi & Co., Ltd., in 2023, bringing together world-class leadership teams and bolstering existing research capabilities and expertise that strengthen Shionogi's longstanding global efforts to develop critically needed antimicrobials. The Qpex senior leadership team worked together for more than a quarter century, and they have completed four regulatory approvals in the past decade. The Qpex team continues to make progress, having advanced three products to U.S. investigational new drug (IND) application during the company's first three years of operations.

About Qpex
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 are 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.

About Qpex and BARDA Partnership
Qpex scientists and clinicians have an extensive track-record of successfully working in public-private partnerships, including a partnership with BARDA that led to the first approved antibiotic drug product under BARDA's Broad Spectrum development programs in 2017. Qpex's current partnership with BARDA is advancing xeruborbactam-based products S-649228 (cefiderocol + xeruborbactam IV) and S-743229 (ceftibuten oral + xeruborbactam oral prodrug). The development of these products in Qpex's portfolio is funded in whole or in part with federal funds from the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, BARDA, under OTA number HHSO100201600026C. To date, BARDA has awarded $92 million and provided technical support. If all options are awarded, the agreement would provide up to $132 million in support for the development of a portfolio of new antibiotics to fight drug-resistant gram-negative infections.

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.

For Further Information, Contact:
SHIONOGI Website Inquiry Form : https://www.shionogi.com/global/en/contact.html

References
1. CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.