



Shionogi Further Extends Infectious Disease Innovation Platform with Planned Acquisition of Qpex Biopharma, Inc.

Acquisition brings access to a novel investigational β -lactamase inhibitor, expanding pipeline of critically needed antimicrobials, and further augments R&D capabilities and expertise

OSAKA, Japan, June 26, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Shionogi Inc., a New Jersey-based subsidiary of Shionogi, has entered into a definitive agreement pursuant to which Shionogi Inc. will acquire Qpex Biopharma, Inc. (Head Office: San Diego; President & CEO: Michael Dudley; hereafter "Qpex"), a privately held clinical stage pharmaceutical company with expertise in antimicrobial research and development. Following the completion of the acquisition, which is subject to customary closing conditions, Qpex will become a wholly owned subsidiary of Shionogi Inc.

"We are pleased to welcome Qpex into the Shionogi family. Bacterial resistance to antibiotics remains one of the biggest threats to global health, and Qpex's pipeline, including xeruborbactam, and its capabilities will accelerate our efforts to develop new antibiotic treatments to address antimicrobial resistance," said Isao Teshirogi, Ph.D., CEO of Shionogi. "Following the close of the acquisition, Qpex will become part of Shionogi, and we will work together to comprehensively address the needs of patients and healthcare professionals and to protect society from current and emerging life-threatening bacterial infections."

"Qpex is thrilled to become part of Shionogi, a world-class organization with an established legacy and commitment to innovation in the development of products for the treatment of infectious diseases," said Michael N. Dudley, PharmD, President and CEO of Qpex. "Joining Shionogi along with our collaboration with BARDA will help drive the availability of new products for treating drug-resistant infections worldwide."

1. Strategic rationale and fit with Shionogi

Qpex's leadership team has a proven track record of discovering novel compounds that target bacteria that are resistant to available antibiotics. This is directly aligned with Shionogi's commitment to "Protect people worldwide from the threat of infectious diseases." Qpex also has specialized expertise in areas of chemistry and molecular design that are complementary to Shionogi's own capabilities, and extensive experience in the development and progression of antimicrobial products, by themselves and in collaboration, which will be immediately useful for the advancement of our combined antibiotic pipeline.

Qpex discovered xeruborbactam,¹ an investigational extended spectrum β -lactamase inhibitor, which is being advanced clinically in both IV and oral² combinations for infections caused by drug-resistant Gram-negative bacteria.

The Qpex acquisition further demonstrates Shionogi's commitment to novel antimicrobial drug research and development and has the potential to accelerate critically needed innovation in infectious disease. The development of the 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, Biomedical Advanced Research and Development Authority (BARDA) under OTA number HHSO100201600026C, a collaboration Shionogi and Qpex intend to continue.

In addition to adding promising investigational compounds to Shionogi's pipeline and expanding the company's expertise in infectious disease research and development to drive future innovation, the acquisition also enables Shionogi to:

- Acquire the exclusive development, manufacturing and marketing rights for xeruborbactam globally
- Advance the development of xeruborbactam, which may be used in combination with other antibiotics to protect against potential future resistance challenges
- Accelerate R&D strategies and create opportunities for collaboration and pipeline expansion in the infectious disease area by leveraging Qpex's internal capabilities and external network, which align well with Shionogi's own

In connection with the closing of the transactions contemplated by the definitive agreement, Shionogi Inc. would make an upfront payment of \$100 million to Qpex equityholders upon completion of the acquisition, and Qpex equityholders may be eligible to receive additional payments based on the achievement of certain regulatory and development milestones, for a total potential additional consideration of \$40 million.

2. Overview of Qpex

Qpex is a resistance-focused infectious disease company on a mission to make both dramatic and sustainable improvements in patient care across both inpatient and outpatient settings.

① Company name	Qpex Biopharma, Inc.
② Head office location	San Diego, U.S.
③ Name of the representative	President & CEO: Michael Dudley, PharmD
④ Established year	2018 (unlisted company)

For more information, please visit <https://www.qpexbio.com/>

3. Resolution Date of Board Meeting

June 21, 2023

4. Agreement Date

June 25, 2023

5. Target Closing Date

Early July 2023 (Scheduled)

6. Future Prospects

Shionogi is still assessing the impact of the addition of Qpex as a subsidiary to its global financial results for the fiscal year ending March 31, 2024.

[About xeruborbactam]

Xeruborbactam is an investigational novel β -lactamase inhibitor with a broad inhibitory spectrum against the β -lactamases that induce resistance to β -lactam antibiotics. β -lactamases have diverse structures and are enzymes that degrade β -lactam antibiotics such as penicillins, cepheems, and carbapenems. Bacteria acquire resistance by inactivating the effects of antibiotics with these enzymes. Xeruborbactam inhibits multiple classes of β -lactamases including metallo-type β -lactamases, found in *Enterobacterales*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* that cannot be inhibited by existing β -lactamase inhibitors, which may provide improved activity when combined with antibiotics.

[About AMR]

Antimicrobial Resistance (AMR) occurs when bacteria, viruses, fungi and parasites change over time and no longer respond to medicines, making infections harder to treat and increasing the risk of disease spread, severe illness and death.³ Bacterial resistance to antibiotics remains one of the biggest threats to global health. In 2019, globally, approximately 1.27 million people died as a result of infections caused by resistant pathogens, surpassing deaths from HIV or malaria.⁴

References

1. Hecker Scott J., et al. Discovery of Cyclic Boronic Acid QPX7728, an Ultrabroad-Spectrum Inhibitor of Serine and Metallo- β -lactamases. *Journal of Medicinal Chemistry*. 2020; 63: 7491–7507. <https://doi.org/10.1021/acs.jmedchem.9b01976>.
2. Nelson, Kirk, et al. In Vitro Activity of the Ultra-Broad-Spectrum Beta-Lactamase Inhibitor QPX7728 in Combination with Meropenem against Clinical Isolates of Carbapenem-Resistant *Acinetobacter baumannii*. *Antimicrobial Agents and Chemotherapy*. 2020; 64 (11). e01406-20. <https://doi.org/10.1128/aac.01406-20>.
3. Antibiotic resistance. World Health Organization website. Accessed February 22, 2023. Available at <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>.
4. Murray, C.J.L, et al. Global burden of bacterial antimicrobial resistance in 2019: A systematic analysis. *The Lancet*. 2022; 399: 629–655. [http://doi.org/10.1016/s0140-6736\(21\)02724-0](http://doi.org/10.1016/s0140-6736(21)02724-0).

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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