PRESSRELEASE

SHIONOGI

IDWeek 2023: Shionogi and Qpex Biopharma, Inc.

Continue Longstanding Commitment to Addressing Unmet Needs in Infectious Disease

OSAKA, Japan, September 8, 2023 - Shionogi & Co., Ltd., (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.), announced the upcoming presentation of new data at IDWeek 2023 (October 11-15, 2023) on its investigational oral antiviral for COVID-19, ensitrelvir (Generic name: ensitrelvir fumaric acid, Code No.: S-217622, hereafter "ensitrelvir"), and Fetroja® (cefiderocol), an antibiotic marketed under the brand name Fetcroja® in Europe.

Shionogi recently extended its infectious disease innovation platform with the acquisition of Qpex Biopharma Inc. (Qpex) in July. The acquisition brings a novel investigational ß-lactamase inhibitor to Shionogi, expanding the company's pipeline of critically needed antimicrobials, and further augmenting its R&D capabilities and expertise.

In addition to Shionogi's data presentations at IDWeek, Olga Lomovskaya, Ph.D., Senior Vice President, Discovery and Clinical Microbiology, Qpex, will present information on xeruborbactam, its investigational ß-lactamase inhibitor, during a session titled, "New Antimicrobials in the Pipeline Part 1," on Thursday, October 12, from 8:00 – 9:00 AM ET.

Shionogi's data presentations at IDWeek include:

Ensitrelvir data:

- Poster #537: Safety and Effectiveness of Ensitrelvir for the Treatment of COVID-19 in Japanese Clinical Practice: A Post-Marketing Surveillance (Interim Analysis)
- Poster #549: Ensitrelvir for the Treatment of COVID-19 Infection: Evaluation of Taste Disorder and Smell Disorder in the Phase 3 Part of the Phase 2/3 SCORPIO-SR Randomized Controlled Trial
- Poster #548: Combined Results of the Phase 2a/2b/3 Randomized Controlled Trials of Ensitrelvir for the Treatment of COVID-19 Infection
- Poster #530: Population Pharmacokinetic Analysis of Ensitrelvir, an Inhibitor of 3C-like (3CL) Protease of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) for Patients with SARS-CoV-2 Infection

Cefiderocol data:

- Poster #2752: Outcomes of Patients with *Stenotrophomonas maltophilia* Infections Treated with Cefiderocol in PROVE (Retrospective Cefiderocol Chart Review) Study

- Poster #2750: *Pseudomonas aeruginosa* Infections Treated with Cefiderocol: Associations of Site of Infection and Time to First Dose with Outcomes in PROVE (Retrospective Cefiderocol Chart Review) Study

- Poster #2751: Cefiderocol Use in Treating Patients with Confirmed *Stenotrophomonas maltophilia* Infections in US Hospitals During January 2020 - June 2022

- Poster #2753: Real-World Use of Cefiderocol Treating Non-COVID Patients with Confirmed Gram-Negative Infections in US Hospitals During January 2020 - June 2022

- Poster #2172: Activity of Cefiderocol and Comparator Agents Against Molecularly Characterized Multidrug-resistant Enterobacterales Clinical Isolates from United States Hospitals (2020-2022)

- Poster #2174: Cefiderocol Activity Against Multidrug-resistant and Molecularly Characterized *Pseudomonas aeruginosa* and *Acinetobacter baumannii-calcoaceticus* complex Clinical Isolates Causing Infection in United States Hospitals (2020–2022)

- Poster #2762: Activity of Cefiderocol and Comparator Agents Against Difficult to Treat Resistance (DTR) Gram-Negative Isolates, Collected During 2020-2022 as Part of SENTRY Antimicrobial Surveillance Program

- Poster #2761: Activity of Cefiderocol and Comparator Agents Against *Achromobacter* and *Burkholderia* Isolates, Collected During 2020-2022 as Part of SENTRY Antimicrobial Surveillance Program

- Poster #2790: Activity of Cefiderocol and Comparator Agents Against Pediatric Isolates of Enterobacterales, *Pseudomonas aeruginosa*, *Acinetobacter baumannii-calcoaceticus* species complex, and *Stenotrophomonas maltophilia* from the SENTRY Surveillance Program (2020-2022)

- Poster #2112: *In vitro* Activity of Cefiderocol and Comparator Agents Against Enterobacterales From United States Hospitals Stratified by Infection Type (2020-2022)

- Poster #2791: Antimicrobial Activity of Cefiderocol and Comparator Agents Against Isolates of *Pseudomonas aeruginosa*, *Acinetobacter baumannii-calcoaceticus* species complex, and *Stenotrophomonas maltophilia* by Infection Type from United States Hospitals in the SENTRY Antimicrobial Surveillance Program (2020-2022)

- Poster #603: Determining Effect of Media and Disk Source on Reproducibility and Relationship between Broth Microdilution and Disk Diffusion Testing of Cefiderocol

For more information, including a complete list of abstracts, please visit https://idweek.org/program/.

During IDWeek, Shionogi will host a Learning Lounge with David Nicolau, PharmD, titled Fetroja® (cefiderocol), An Overview of *In Vitro* and Clinical Data on Friday, October 13, from 10:15 – 11:00 AM ET. Shionogi will also host a symposium titled Acute and Long COVID-19 Management Post-Pandemic: To 2024 and Beyond, an Industry Education Evening (Non CE) on Saturday, October 14, from 7:00 – 9:00 PM ET.

About Shionogi in Infectious Disease
Since 1953 Shionogi has been a leader in infectious disease discovery and commercialization. Our R&D story extends beyond antibiotics to include novel medications for HIV and influenza. Today, our global pipeline

includes investigational agents developed to address global health challenges including antimicrobial resistance, COVID-19, influenza, rare fungal diseases and respiratory syncytial virus.

As part of our commitment to addressing unmet medical needs, Shionogi is partnering with several non-governmental organizations to increase equitable access to our medications worldwide. Shionogi has a landmark license and technology transfer agreement for cefiderocol with Global Antibiotic Research and Development Partnership (GARDP) and a collaboration agreement with the Clinton Health Access Initiative (CHAI) to transform the landscape of access to antibiotics in many low-income countries, most lower middle- and upper middle-income countries, and select high-income countries. We also have a voluntary license agreement with the Medicines Patent Pool (MPP) to facilitate additional production and distribution of ensitrelvir, pending regulatory authorization or approval, by granting sublicences to qualified generic manufacturers, with the goal of expanding access to people living in low- and middle-income countries (LMICs).

For Full Prescribing Information, including approved Indications and Important Safety Information about our marketed product(s), please visit https://www.shionogi.com/us/en/products.html.

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