FOR MEDICAL AND TRADE MEDIA ONLY

Shionogi announces agreement with SOBI on Fetcroja®▼ (cefiderocol) to expand access for patients with infections due to aerobic Gram-negative organisms in adults with limited treatment options.

- Shionogi and Sobi have signed a distribution agreement for cefiderocol covering 13 countries in Central & Eastern Europe (CEE)

- Cefiderocol provides coverage against all Gram-negative pathogens considered of critical priority by the World Health Organisations (WHO) – carbapenem-resistant Acinetobacter baumannii, Pseudomonas aeruginosa and Enterobacterales[i,ii]

Amsterdam, Netherlands, 18 December 2023–Shionogi B.V., the European subsidiary of SHIONOGI & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced today that they have signed a distribution agreement with Swedish Orphan Biovitrum AB (publ) ("Sobi") for Fetcroja® (cefiderocol) in Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Slovakia, Slovenia, Cyprus, Estonia, Greece, Latvia and Lithuania.

Leveraging the company's commercial capabilities and supply chain networks, Sobi will promote and commercialize cefiderocol in the markets, while Shionogi will act as marketing authorization holder.

Antimicrobial resistance (AMR) is one of the top 10 global public health threats, which must be urgently addressed. AMR is widespread across the European Continent but is higher across the southern and eastern parts of the region.[iii]

Huw Tippett, Chief Executive Officer, Shionogi B.V., the subsidiary of Shionogi in Europe, said: "We are delighted to collaborate with Sobi to accelerate patient access within Europe to our innovative antibiotic, cefiderocol for patients suffering from multi drug resistant Gram-negative infections with limited treatment options. Collaborating with industry partners is fundamental to how Shionogi accelerates patient access and improved treatment outcomes in infectious disease across the healthcare community."

"Cefiderocol is a highly welcomed addition to Sobi's specialty care portfolio in central eastern Europe, Greece and Cyprus and fits well with our established infrastructure," said Konstantin Bakaykin, Sobi's Vice President and General Manager for CEER & Japan. "We are looking forward to bringing this life saving antibiotic to the patients in need. We are excited to enter into this partnership with Shionogi, a company sharing the same patient centric values as Sobi and look forward to launching cefiderocol from 2024."

About Shionogi in Infectious Disease and AMR

Shionogi B.V. (known as "Shionogi Europe") is the European headquarters of Shionogi & Co., Ltd, a leading global research-driven pharmaceutical company based in Osaka, Japan. Shionogi is dedicated to finding innovative solutions for pressing unmet clinical needs, with a strong track record in discovering and developing novel medicines for antimicrobial resistance (AMR), HIV and influenza. Alongside its work in infectious diseases, the company strives to find solutions in other therapy areas affecting quality of life.

Shionogi Europe has a unique DNA, combining Japanese roots with a strong and rapidly growing European operation. With five fully operational affiliate offices, additional geographical reach and influential research & development partnerships, Shionogi Europe is making a positive impact for patients, communities and the industry by shaping the future of healthcare.

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.

Shionogi is proud to be one of the few large pharmaceutical companies that continues to focus on research and development in anti-infectives. The company invests the highest proportion of its pharmaceutical revenues in relevant anti-infectives R&D compared to other large pharmaceutical companies .[iv]

To read more about Shionogi Europe's commitment to AMR check here: Antimicrobial Resistance

Resistant Gram-negative infections

The increasing resistance of many infections caused by Gram-negative bacteria to existing therapies, including carbapenem-resistant Enterobacterales and non-fermenting species such as *P. aeruginosa, A. baumannii*, and *S. maltophilia*, makes them difficult to treat and results in high mortality rates. The World Health Organization have identified carbapenem-resistant strains of Enterobacterales, *P. aeruginosa* and *A. baumannii* as the top priority in the research and development of new antibiotics. Cefiderocol is the first antibiotic to address all three major mechanisms of carbapenem-resistance and is an important treatment option to address this urgent unmet need.

About cefiderocol

Cefiderocol is a siderophore cephalosporin antibiotic with an innovative mechanism for penetrating the outer cell membrane of Gram-negative pathogens by acting as a siderophore. In addition to entering cells by passive diffusion through porin channels, cefiderocol binds to ferric iron and is actively transported into bacterial cells through the outer membrane via the bacterial iron transporters, which function to incorporate this essential nutrient for bacteria. These mechanisms allow cefiderocol to achieve higher concentrations in the periplasmic space where it can bind to penicillin-binding proteins and inhibit cell wall synthesis in the bacterial cells. Cefiderocol has also demonstrated in vitro activity against certain bacteria that contain very problematic resistant enzymes such as

ESBLs, AmpC, serine- and metallo-carbapenemases. Data from multinational surveillance studies for cefiderocol demonstrated potent in vitro activity against a wide spectrum of Gram-negative pathogens including carbapenem-resistant *A. baumannii, P. aeruginosa,* Enterobacterales, and *S. maltophilia.* The clinical significance of the *in vitro* data is unknown. Cefiderocol has no clinically relevant activity against Gram-positive or anaerobic bacteria.

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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