

## Press Release

### **Shionogi & Co., Ltd. and F2G Ltd., Enter Strategic Collaboration to Develop and Commercialize the New Antifungal Agent Olorofim in Europe and Asia**

- *Shionogi to conduct clinical trials, subsequent registration, and commercialization of olorofim for invasive aspergillosis (IA) in Europe and Asia*
- *F2G to receive upfront payment of \$100m and share development costs*
- *F2G will also be eligible for additional regulatory and commercial milestones of up to \$380m, as well as double-digit royalties on net sales*

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**OSAKA, Japan, and MANCHESTER, UK, May 16, 2022** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") and F2G Ltd. (Head Office: Manchester, UK; CEO: Francesco Maria Lavino; hereafter "F2G") today announced that they have entered a strategic collaboration to develop and commercialize the new antifungal agent olorofim for invasive fungal infections in Europe and Asia.

Olorofim is a novel oral antifungal therapy developed by F2G to treat invasive aspergillosis (IA) and other rare mold infections. Olorofim works through a unique mechanism of action, different from existing classes of antifungals, exerting fungicidal activity through inhibition of the pyrimidine synthesis pathway. Olorofim represents the first novel antifungal class developed in the past 20 years and is the only antifungal medication to be awarded a Breakthrough Therapy Designation (BTD) for multiple indications by the FDA.

Under the terms of the agreement, Shionogi will conduct the clinical trials and subsequent registration and commercialization of olorofim for IA in Europe and Asia. Shionogi will make an upfront payment to F2G of \$100 million and share development costs in global studies. F2G will also be eligible to receive additional regulatory and commercial milestones of up to \$380 million, as well as double-digit royalties on net sales.

“We are delighted to announce this partnership. By joining forces with Shionogi, we will be able to progress the development of olorofim with a partner which has a proven track record in both global drug development and business development to effectively deliver a potentially life-saving therapy to patients globally,” said Francesco Maria Lavino, Chief Executive Officer of F2G. “As F2G prepares to commercialize olorofim in the US, we are excited to work closely together with Shionogi to address the unmet medical need caused by invasive aspergillosis and other rare mold diseases around the world.”

“Shionogi is committed to ‘Protect people worldwide from the threat of infectious diseases’ as our key focus. We are pleased to partner with F2G, which is boldly tackling fungal infections where new drug development is difficult.” said Isao Teshirogi, Ph.D., CEO of Shionogi. “We will continue to address unmet medical needs in infectious diseases, and to work towards total care for this area. As part of this mission and through our partnership with F2G, we hope to be able to provide new antifungal drugs to patients to protect people's health from life-threatening, invasive fungal infections.”

Invasive aspergillosis is a rare disease that can be fatal, occurring primarily in immunocompromised patients, including those having received cancer chemotherapy or hematopoietic stem cell transplantation. Other rare fungi, such as scedosporium or lomentospora, may also infect patients with compromised immunity. Existing antifungal therapies may not be appropriate treatments due to drug-drug interactions, tolerability or other serious side-effects, or are not effective due to resistance. For these patients, treatment options are limited.

Olorofim is anticipated to be used to treat patients with serious invasive fungal disease where existing treatments are inappropriate or no longer effective. Both companies believe olorofim provides hope to patients with, and physicians treating, serious invasive fungal infections.

### **About Shionogi**

Shionogi & Co., Ltd. is a leading global research-driven pharmaceutical company based in Japan, dedicated to bringing benefits to patients based on its corporate philosophy of “supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” The company has discovered and developed novel medicines for HIV, influenza and antimicrobial resistance, and currently markets products in several therapeutic areas including anti-infectives with the first siderophore cephalosporin, cefiderocol. For more information, please visit <https://www.shionogi.com/global/en/>.

### **About F2G**

F2G is a biotech company with operations in the UK, US, and Austria focused on the discovery and development of novel therapies to treat potentially life-threatening invasive fungal infections. F2G has discovered and developed a completely new class of antifungal agents called the orotomides which selectively target a key enzyme in the de novo pyrimidine biosynthesis pathway. This is a completely different mechanism from that of the currently marketed antifungal agents and gives the orotomides fungicidal activity against a broad range of rare and resistant fungal mold infections. For more details, please visit the [F2G web site](#).

### **About olorofim**

Olorofim (formerly, F901318) is F2G’s leading candidate from the orotomide class and is currently in a Phase 2b open-label study<sup>1</sup>. F2G is currently initiating a global Phase 3 trial (“OASIS”)<sup>2</sup> to compare treatment with olorofim versus AmBisome<sup>®</sup> followed by standard of care (SOC) in patients with lower respiratory tract invasive fungal disease caused by proven or probable infection with *Aspergillus* species. Olorofim has received orphan drug status from the European Medicines Agency for the treatment of invasive aspergillosis and invasive scedosporiosis. Olorofim has also received orphan drug status from the FDA for the treatment of coccidioidomycosis scedosporiosis, and invasive aspergillosis. Olorofim has been granted Qualified Infectious Disease Product (QIDP) designation for invasive aspergillosis, invasive scedosporiosis, invasive lomentosporiosis, coccidioidomycosis, invasive disease due to *Scopulariopsis* species, and invasive fusariosis.

### **About invasive aspergillosis**

Aspergillosis is a fungal infection caused by *Aspergillus* species of mold which are commonly found all over the world. Most of these molds, in most people, are harmless. However, aspergillus is transmitted to humans through inhalation and may cause a broad spectrum of disease ranging from hypersensitivity reactions to direct invasion and destruction of tissue. Invasive aspergillosis is a rare disease that can occur in over 10% of some high-risk immunosuppressed populations with mortality exceeding 80%.

**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.*

**References**

1. <https://clinicaltrials.gov/ct2/show/NCT03583164>
2. <https://clinicaltrials.gov/ct2/show/NCT05101187>

**For Further Information, Contact:**

SHIONOGI Website Inquiry Form <https://www.shionogi.com/global/en/contact.html>.

For F2G, contact Petra Taylor-Stadler

Email: [ptaylor@f2g.com](mailto:ptaylor@f2g.com)

Tel: +43 (0)1 997 4267

Optimum Strategic Communications

Mary Clark/ Charlotte Hepburne-Scott/ Supriya Mathur/ Zoe Bolt

Email: [F2G@optimumcomms.com](mailto:F2G@optimumcomms.com)

Tel: +44 (0) 203 882 9621