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F2G and Shionogi Announce Positive Topline Results from Global Phase 3 OASIS Study Evaluating Oral Olorofim Versus AmBisome® Followed by Standard of Care in Patients with Invasive Aspergillosis

- *The study achieved the primary endpoint of non-inferiority, with a rate of all-cause mortality (ACM) at Day 42 for olorofim of 23.8% and for AmBisome® followed by standard of care of 24.3%*
- *No new safety findings were observed*
- *The rate of drug-related treatment-emergent adverse events (TEAEs) was 35.8% for olorofim and 63.9% for AmBisome® followed by standard of care*
- *The study enrolled patients with invasive aspergillosis whose infection was either refractory to or unsuitable for azole therapy*
- *If approved, olorofim will be the first novel mechanism agent for the treatment of invasive aspergillosis in over 20 years*[1,2]

STRICTLY EMBARGOED UNTIL 00:01 EASTERN STANDARD TIME 18 JUNE 2026

MANCHESTER, United Kingdom, OSAKA, Japan – June 18, 2026 – F2G Ltd and Shionogi & Co., Ltd (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D) ("Shionogi") today announced positive topline results from the global Phase 3 OASIS study (NCT05101187), comparing the investigational oral antifungal drug olorofim versus AmBisome® (liposomal amphotericin B for injection) followed by standard of care (SOC) in patients with invasive aspergillosis whose infection is either refractory to or unsuitable for azole therapy.

The study met its primary endpoint of non-inferiority, with a rate of all-cause mortality (ACM) at Day 42 for olorofim of 23.8% vs. 24.3% for AmBisome® followed by SOC (difference of -0.5% with 95% confidence interval of -13.1 to 10.8%). No new safety findings were observed for olorofim; the rate of drug-related treatment-emergent adverse events (TEAEs) was 35.8% for olorofim and 63.9% for AmBisome® followed by standard of care with the difference mainly driven by the higher rate of renal events in the AmBisome arm.

These results expand on the previous Phase 2b study data that led to olorofim's Breakthrough Therapy Designations from the U.S. Food and Drug Administration (FDA), reinforcing olorofim's potential as a treatment for patients with invasive aspergillosis[1,3]. F2G and Shionogi plan to present pivotal results from the study at a future medical congress. These data will be submitted to regulatory authorities in the U.S. by F2G and in Europe and Asia by Shionogi.

"Invasive fungal infections remain difficult to treat and can be life-threatening especially in immunocompromised patients," said Johan Maertens, MD, PhD, Professor of Hematology at University Hospitals Leuven, Belgium, the study's Principal Investigator. "The OASIS topline results add to the growing body of evidence supporting olorofim's therapeutic potential in a hard-to-treat population with limited antifungal options. We're hopeful this could offer a meaningful alternative for clinicians to treat challenging infections caused by *Aspergillus*."

Francesco Maria Lavino, Chief Executive Officer of F2G, commented, "We are encouraged by the topline results from the Phase 3 OASIS study, which represent an important milestone for F2G and for our collaboration with Shionogi. These findings demonstrate the potential for olorofim to serve as a new option for patients with difficult to treat invasive fungal infections, including invasive aspergillosis. We are grateful to the patients, investigators, our partner Shionogi and to the F2G team for their dedication to this pivotal study."

Dr John Keller, Director of the Board, Senior Vice President, R&D, Shionogi & Co., Ltd., added, "This is a promising new development in antifungal medicine – an area where patients have been under-served for more than 20 years. In current clinical practice, safety and tolerability considerations, particularly effects on renal function, can pose significant challenges for treatment selection and continuation. Against this background, the results of the OASIS study suggest that olorofim has the potential to offer a new treatment option for patients with invasive aspergillosis." Dr Keller continued: "As a leader in infectious disease R&D, our partnership with F2G for a new class of antifungal treatment supports our commitment to advancing innovation across all anti-infective medicine for some of the most challenging disease areas. We look forward to sharing the full results in due course."

Invasive aspergillosis is a life-threatening fungal infection that primarily affects immunocompromised patients and is associated with substantial morbidity and mortality[4]. Treatment options are limited for patients who cannot be treated with available azole antifungal therapies[1].

F2G and Shionogi are collaborating to develop and commercialize olorofim and bring this novel antifungal therapy to patients with invasive fungal infections. F2G has commercial responsibility for olorofim in North America and non-Shionogi territories, and Shionogi has commercial responsibility for olorofim in Europe and Asia.

About the Phase 3 OASIS Study

The Phase 3 OASIS (Olorofim Aspergillus Infection Study) trial (NCT05101187) was a global, randomized study that evaluated the efficacy and safety of olorofim versus AmBisome®

followed by standard of care in adult patients with invasive aspergillosis whose infection is either refractory to or unsuitable for azole therapy. Invasive aspergillosis is a life-threatening fungal infection with limited treatment options due to rising drug resistance and toxicity concerns[1,2,4]. The study's primary endpoint was all-cause mortality at Day 42, with additional measures of clinical response, safety, and quality of life.

About Olorofim

Olorofim (formerly, F901318) is F2G's leading candidate from the orotomide class and has been studied in a recently completed a global Phase 3 trial ("OASIS", NCT05101187). Olorofim is a first-in-class antifungal with a novel mechanism of action, oral dosing, and activity against a wide range of *Aspergillus* species, including strains that are resistant to currently approved agents[1]. If approved based on the Phase 3 OASIS data, olorofim will be the first novel mechanism agent for invasive aspergillosis in more than 20 years[1,2].

In the U.S., olorofim has received orphan drug status from the FDA for the treatment of invasive aspergillosis, scedosporiosis, invasive scopulariopsis, and coccidioidomycosis[5]. Olorofim has been granted Qualified Infectious Disease Product (QIDP) designation for several invasive fungal infections, including invasive aspergillosis and coccidioidomycosis[1].

Additionally, olorofim has also received two Breakthrough Therapy designations (BTD) from the FDA[1]. The first BTD was for the treatment of invasive mold infections in patients with limited or no treatment options, including aspergillosis refractory or intolerant to currently available therapy, and infections due to *Lomentospora prolificans*, *Scedosporium* and *Scopulariopsis* species[1]. The second BTD was for the treatment of central nervous system (CNS) coccidioidomycosis refractory or otherwise unable to be treated with standard of care therapy[1].

In Europe, olorofim has been granted orphan designation from the European Medicines Agency for the treatment of invasive aspergillosis, scedosporiosis, and invasive scopulariopsis[1].

Olorofim is an investigational therapy and has not been approved by any regulatory authorities.

About F2G

F2G is a clinical-stage biopharmaceutical company with operations in the UK, U.S., 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 pyrimidine biosynthesis pathway, a novel mechanism of action that is distinct from currently marketed antifungal agents. This mechanism provides the orotomides with fungicidal activity against a broad range of rare and resistant fungal mould infections. For more information, please visit: www.f2g.com

About Shionogi & Co., Ltd.

Shionogi & Co., Ltd. is a 148-year-old global, research-driven pharmaceutical company headquartered in Osaka, Japan, that is 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 currently markets products in several therapeutic areas including anti-infectives, pain, CNS disorders. Shionogi's research and development currently targets two therapeutic areas: infectious diseases and diseases with unmet medical needs in pain/CNS, including Alzheimer's disease, oncology, rare diseases, and sleep apnea. For more information on Shionogi & Co., Ltd., please visit https://www.shionogi.com/global/en.

Shionogi 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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