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F2G and Shionogi Report Data from Global Phase 3 OASIS Study Evaluating Investigational Oral Olorofim Versus AmBisome® Followed by Standard of Care in Invasive Aspergillosis in Late-Breaking Oral Presentation at IDWeek 2026

- *Oral olorofim was non-inferior to AmBisome® followed by standard of care (AmBisome®+SOC), with Day 42 all-cause mortality of 23.8% for olorofim versus 24.3% for AmBisome®+SOC in patients with invasive aspergillosis*[1]
- *Enrolled patients had invasive aspergillosis for which standard mould-active azole therapy was either not appropriate (known or suspected azole resistance, intolerance to azole therapy, drug-drug interactions, or breakthrough infection while on azole) or had been ineffective*[1]
- Fewer patients had at least one investigator-attributed adverse event in the olorofim arm than in the AmBisome®+SOC arm: 35.8% vs. 63.9% for all drug-related adverse events and 4.0% vs. 18.1% for serious drug-related adverse events[1]
- *If approved, oral olorofim will be the first novel mechanism antifungal for invasive aspergillosis in over 20 years.*[2,3] *Its novel mechanism of action gives it fungicidal activity against Aspergillus species, including azole-resistant strains*[3]

MANCHESTER, United Kingdom and OSAKA, Japan, Oct. 21, 2026 (GLOBE NEWSWIRE) -- F2G Ltd (Head Office: Manchester, UK; Chief Executive Officer: Francesco Maria Lavino) and Shionogi & Co., Ltd (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D) ("Shionogi") today announced results from the global Phase 3 OASIS study (NCT05101187), which will be featured in a late-breaking oral presentation at IDWeek 2026 on October 22, 2026. The study demonstrated that oral olorofim was non-inferior to AmBisome® (liposomal amphotericin B for injection) followed by standard of care (AmBisome®+SOC) in adult patients with invasive aspergillosis whose infection is either refractory to or inappropriate for azole therapy.[1] 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.[3]

These data will be submitted to regulatory authorities in the U.S. by F2G and in Europe and Asia by Shionogi. F2G anticipates resubmitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) by the end of 2026.

Efficacy and Safety Results

- The study randomized 225 patients (151 in the olorofim arm, 74 in the AmBisome®+SOC arm) and met its primary endpoint of non-inferiority within a pre-specified margin of 20%: the rate of all-cause mortality (ACM) at Day 42 for olorofim was 23.8% (36/151) vs. 24.3% (18/74) for AmBisome®+SOC (difference of -0.5% with 95% confidence interval (CI) of -13.1 to 10.8%)[1]
- The study showed similar efficacy rates in key secondary efficacy endpoints:
  - The Mycoses Study Group - European Organization for Research and Treatment of Cancer (MSG-EORTC) global response as determined by an independent Data Review Committee was 26.5% (40/151) vs. 31.1% (23/74) at Day 42 and 30.5% (46/151) vs. 28.4% (21/74) at Day 84 for olorofim vs. AmBisome®+SOC, respectively. Successful global response requires improvement of all three of its clinical, radiological and mycological subcomponents.[1]
  - The rate of all-cause mortality (ACM) at Day 84 for olorofim was 32.5% (49/151) vs. 29.7% (22/74) for AmBisome®+SOC (difference of 2.7% with 95% CI of -10.6 to 15.0%)[1]
- The number of patients with at least 1 drug-related adverse event was 35.8% (54/151) for olorofim and 63.9% (46/72) for AmBisome®+SOC. This difference was driven by fewer patients having drug-related renal adverse events with olorofim (1.3% [2/151]) vs. AmBisome®+ SOC (22.2% [16/72])[1]
- Drug-induced liver injury (DILI) remains an important safety signal for olorofim as well as other antifungal agents.[1,5] The rate of DILI events adjudicated by expert review as at least possibly related to study therapy was similar in the safety population of the two arms: 4.6% (7/151) vs. 4.2% (3/72) for olorofim and AmBisome®+SOC, respectively.[1]
- Additionally, patients treated with olorofim were discharged from the hospital earlier (17±15 days) vs. AmBisome®+SOC (28±25 days).[1]

"We continue to be encouraged by these data suggesting that olorofim could offer an oral alternative for patients with invasive aspergillosis in a setting where patients who cannot receive effective mould-active azole therapy currently rely on intravenous non-azole options," said Johan Maertens, MD, PhD, Professor of Hematology at University Hospitals Leuven, Belgium, the study's Principal Investigator. "Having an oral option like olorofim, with data supporting its safety in challenging patients, including those with complex drug interactions, would give me another valuable tool in the fight against this fungal infection."

These data build on the previous Phase 2b data showing efficacy and good tolerability in patients with few or no treatment options for a range of invasive fungal diseases, including invasive aspergillosis.[6]

John H. Rex, MD, Chief Medical Officer of F2G, commented, "Olorofim is a first-in-class molecule with a novel mechanism of action, the first such advance in more than 20 years. The growing body of

evidence shows it to be active against *Aspergillus* species, including azole-resistant strains. We are grateful to the patients, investigators, our partner Shionogi, and the F2G team for their dedication to advancing olorofim."

Dr. John Keller, Director of the Board, Senior Vice President, R&D, Shionogi & Co., Ltd., commented, "For over 20 years, there has been no significant innovation in therapies for invasive aspergillosis, which highlights the importance of the OASIS study results. We are proud to be a part of this exciting milestone in the development of novel therapies for invasive fungal infections in patients who have, to date, had very limited treatment options."

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

About the Phase 3 OASIS Study

The Phase 3 OASIS (Olorofim Aspergillus Infection Study) trial (NCT05101187) was a global, adjudicator-blinded study that randomized 225 adults with proven invasive aspergillosis or probable pulmonary invasive aspergillosis (IA) for whom a mould-active azole antifungal was inappropriate.[1] Patients were enrolled at diagnosis based on known or suspected azole resistance, intolerance to azole therapy, drug-drug interactions with azole treatment, breakthrough infection while on azole prophylaxis, or failure of prior azole therapy.[1]

The majority (~79%) of patients had hematologic malignancies and/or had undergone stem cell transplantation, ~11% had received a solid organ transplant, and ~40% were neutropenic at enrollment or during the four preceding calendar days.[1] Patients were randomized 2:1 to receive up to 84 days of either oral olorofim (n=151; 150 mg twice daily [BID] on day 1, then 90 mg BID, with dose adjustments permitted for concomitant therapies and clinical circumstances) or intravenous (IV) AmBisome® (n=74; 3 mg/kg QD) for at least 10 days (unless discontinued earlier due to toxicity) followed either by continued AmBisome® or by other standard of care antifungal agents with comparator agents adjusted per product labeling and local, national, or international guidelines.[1]

The primary endpoint was Day 42 All-Cause Mortality (ACM) in the ITT (all patients randomized) population using an FDA- and CHMP-agreed non-inferiority margin of 20%.[1] The secondary endpoints were Day 84 ACM and global response at Day 42 and Day 84 in the ITT population.[1]

About Olorofim

Olorofim (formerly, F901318) is F2G's leading candidate from the orotomide class and has been studied in a recently completed 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.[3] 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.[2,3]

In the U.S., olorofim has received orphan drug status from the FDA for the treatment of invasive aspergillosis, scedosporiosis, invasive scopulariopsis, and coccidioidomycosis.[7] Olorofim has been granted Qualified Infectious Disease Product (QIDP) designation for several invasive fungal infections, including invasive aspergillosis and coccidioidomycosis.[3]

Additionally, olorofim has also received two Breakthrough Therapy designations (BTD) from the FDA.[3] The first BTD was for the treatment of invasive mould 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.[3] 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.[3]

In Europe, olorofim has been granted orphan designation by the European Commission following review by the European Medicines Agency for the treatment of invasive aspergillosis, scedosporiosis, invasive scopulariopsis, and coccidioidomycosis.[3,8]

Olorofim is an investigational therapy. Regulatory authorities have not established its safety and efficacy and it 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 and cardiovascular diseases. Shionogi's research and development currently targets two therapeutic areas: infectious diseases and diseases with unmet medical needs, including rare diseases, allergy/inflammation, oncology, hearing loss, 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.

SHIONOGI Website Inquiry Form: https://www.shionogi.com/global/en/contact.html Shionogi Europe Press Office: pressoffice@shionogi.eu

F2G Media Contact:
Gloria Gasaatura
LifeSci Communications
F2GMedia@lifescicomms.com

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