F2G Receives Complete Response Letter from FDA for New Drug Application for Olorofim for The Treatment of Invasive Fungal Infections; Plans Resubmission With Additional Data and Analyses

- *Complete Response Letter is related to the request for additional data and analyses.*
- *F2G remains committed to bringing olorofim to patients and intends to meet with FDA in the coming months to align on next steps to obtain approval using the full data set from pivotal clinical Study 32.*
- *F2G along with its partner Shionogi & Co., Ltd. is enrolling patients with invasive aspergillosis in a global Phase 3 study to compare treatment with olorofim versus AmBisome® followed by standard of care.*

MANCHESTER, United Kingdom, June 15, 2023 – F2G Ltd. today announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for olorofim, an investigational antifungal, for the treatment of invasive fungal infections in patients who have limited or no treatment options.

According to the CRL, FDA was not able to approve olorofim at this time, requesting additional data and analyses. The additional information requires time and resources that extend beyond the current review period. The FDA encouraged the company to work with the agency to plan for the new analyses and develop the NDA package.

The initial NDA included data from the first 100 patients enrolled in the then-ongoing Phase 2b single-arm, open-label study (Study 32, NCT03583164). The NDA was accepted for review by the FDA with a PDUFA target action date set for June 17, 2023. Study 32 has now completed enrollment with a total of 203 patients, and the full data set is planned to be submitted as part of the revised NDA package.

“While F2G is disappointed with this outcome, we remain optimistic about olorofim’s potential to address an unmet need for patients with invasive fungal infections who have exhausted their treatment alternatives,” said Francesco Maria Lavino, chief executive officer of F2G. “We are assessing the details of the CRL and we plan to meet with the FDA to discuss it further, but we are confident that we can identify a regulatory path forward in the US.”

In parallel, F2G continues to expand olorofim’s clinical development program, and along with its partner Shionogi & Co., Ltd. is enrolling patients with proven or probable invasive aspergillosis in a global Phase 3 trial (“OASIS”) to compare treatment with olorofim versus AmBisome® followed by standard of care (NCT05101187). F2G has commercial responsibility for olorofim in North America, and Shionogi has commercial responsibility for olorofim in Europe and Asia Pacific.

About Olorofim

Olorofim (formerly, F901318) is F2G’s leading candidate from the orotomide class. A Phase 2b single-arm open-label study in patients who have limited treatment options for difficult-to-treat invasive, rare fungal mold infections such as azole-resistant aspergillosis, scedosporiosis, lomentosporiosis, and other rare mold infections has recently completed enrollment. To expand on the studied patient population, F2G has initiated a global Phase 3 trial (“OASIS”) to compare treatment with olorofim versus AmBisome® followed by standard of care (SOC) in patients with proven or probable invasive fungal infection due to *Aspergillus* species (NCT05101187). Olorofim has received orphan drug designation from the FDA for the treatment of coccidioidomycosis, scedosporiosis (including lomentosporiosis), invasive *Scopulariopsis*, and invasive aspergillosis. Olorofim has also received orphan drug designation from the European Medicines Agency (EMA) for the treatment of invasive aspergillosis, invasive scedosporiosis (including lomentosporiosis), and invasive *Scopulariopsis*. 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. Olorofim has received Breakthrough Therapy Designation for both “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" and "treatment of Central Nervous System (CNS) coccidioidomycosis refractory or otherwise unable to be treated with standard of care therapy." Olorofim is not approved by the FDA or any other regulatory agency.

Invasive fungal infections cause substantial morbidity and mortality, particularly among immunosuppressed patients, and can prove to be lethal in also healthy individuals when they get into deeper tissues. Effective therapies do not currently exist for some of these fungi. And even when therapies exist, some patients with invasive infections may be refractory or unable to tolerate existing antifungal treatments, thus underscoring the urgent need for new and effective treatments

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 information, please visit: www.f2g.com

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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