**F2G Announces FDA Filing Acceptance of New Drug Application for Olorofim for the Treatment of Invasive Fungal Infections**

- *Application submitted under priority review with PDUFA target action date set for June 17, 2023*
- *NDA submission is based on positive data from ongoing Phase 2b open-label study of oral olorofim in 100 patients with invasive fungal infections with limited or no treatment options*
- *F2G is continuing preparations for a possible U.S. commercial launch of oral olorofim in 2nd half of 2023*

PRINCETON, New Jersey, December 19, 2022 – F2G Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing its New Drug Application (NDA) for olorofim for the treatment of invasive fungal infections in patients who have limited or no treatment options.

F2G has requested approval of the NDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway) for a limited, well-defined population with invasive fungal infections and limited or no treatment options. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of June 17, 2023

The NDA is supported by strong efficacy data and a good tolerability profile seen during treatment of the first 100 patients in the Phase 2b open-label study, all of whom had limited or no treatment options for either proven invasive fungal infection (including aspergilllosis, *lomentosporiosis, scedosporiosis, Scopulariopsis* infections, and refractory extrapulmonary *coccidioidomycosis*) or probable pulmonary invasive aspergillosis (Study 32, NCT03583164).

“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,” said John H. Rex, MD, chief medical officer of F2G. “Olorofim is a novel mechanism antifungal therapy from the newly discovered orotomide class. It provides a new option for patients who have exhausted treatment alternatives.”

Francesco Maria Lavino, chief executive officer of F2G, added, “We are committed to addressing rare fungal infections, and the acceptance of filing of olorofim NDA for use in this well-defined and high-need population marks a major milestone toward our goal of bringing new options to these patients. We are building an experienced commercial team in preparation for U.S. launch, pending FDA approval. If approved, olorofim will be the first of a new class of antifungal drugs.”

Olorofim is the only antifungal medication to be awarded Breakthrough Therapy Designation by the FDA. Olorofim works through a novel mechanism of action, different from existing classes of antifungals, exerting fungal cell death through inhibition of the enzyme dihydroorotate dehydrogenase (DHODH) in the pyrimidine synthesis pathway. It is active *in vitro* against *Aspergillus* spp. (including azole-resistant and cryptic species), rare molds (e.g., *Lomentospora prolificans*, *Scedosporium spp.*, *Scopulariopsis spp.*), and dimorphic fungi (e.g., *Coccidioides* spp.).

## About Olorofim

Olorofim (formerly, F901318) is F2G's leading candidate from the orotomide class and is currently being investigated in a Phase 2b 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. 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.

## 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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