

F2G Ltd Receives European Orphan Drug Designation for its Lead Candidate F901318

MANCHESTER, UK – 09 January 2017 – F2G Ltd, a UK Biotech developing novel therapies for life threatening fungal infections, today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products has granted orphan drug status to its lead clinical candidate, F901318, for the treatment of invasive Aspergillosis and rare mould infections caused by *Scedosporium* species.

Orphan drug designation will allow F901318 up to ten years market exclusivity following market authorisation in the EU.

F901318 is the first member of a novel class of systemic antifungal agents targeting life threatening mould infections and acting through a completely novel cellular target. F901318 is being developed for both intravenous and oral formulations and will enter Phase II clinical development in mid-2017.

Dr John H. Rex, Chief Medical Officer, F2G Ltd, said: “Given the global acknowledgement of increasing resistance of moulds to the azole antifungal class, we are delighted that the EMA has granted orphan drug status to F901318. We believe this agent will offer important therapeutic options to clinicians treating these deadly infections.”

Ian Nicholson, Chief Executive Officer, F2G Ltd, added: “Receiving the European orphan drug designation for F901318 offers certain benefits and incentives, including marketing exclusivity, that are strategically important from a regulatory and commercial perspective. The positive decision of the EMA orphan drug committee is further validation of F901318 and our development program as we look forward to accelerating our Phase II clinical programme this year.”

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About European Union (EU) Orphan Drug Designation: The European Commission grants orphan drug designation status to provide incentives to develop medicinal products to treat, prevent or diagnose diseases or conditions that affect no more than five in 10,000 persons in the European Union.

About F2G Ltd: F2G is a world-leading UK biotech company focused on the discovery and development of novel therapies to treat life threatening invasive fungal infections, with experienced management & board. F2G has discovered and developed a completely new class of antifungal agents called the orotomides. The orotomides are active against *Aspergillus* and other rare and resistant moulds and act via a completely different mechanism than currently marketed antifungal agents. Due to their new mechanism of action, orotomides are active against fungal infections resistant to current therapies, a growing problem globally. A limited Phase II study for F901318 is planned imminently with pivotal registration trials in Invasive Aspergillosis planned for 2017 based on an accelerated regulatory pathway agreed with the relevant agencies. F901318 is being developed both as IV and oral formulations and promises to have a safe and well-tolerated profile. The company recently announced a \$60 million financing to develop its pipeline of novel therapies to treat life threatening invasive fungal infections.

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