

MANCHESTER UK, NOVEMBER 30TH 2015. F2G Ltd, a UK based antifungal drug discovery and development company, today announced that its novel systemic antifungal product F901318 has been accepted to participate in the European Medicines Agency's (EMA) Adaptive Pathways pilot programme.

Initiated in March 2014, the Adaptive Pathways (formerly Adaptive Licensing) pilot programme forms part of the EMA's strategy to provide improved access to new therapies treating serious conditions where there is a high unmet medical need.

The concept of Adaptive Pathways foresees either an initial approval in a well-defined patient subgroup with a high medical need and subsequent widening of the indication to a larger patient population, or an early regulatory approval (e.g. conditional approval) which is prospectively planned, and where uncertainty is reduced through the collection of post-approval data on the medicine's use in patients. This approach is particularly relevant for medicines with the potential to treat serious conditions with an unmet medical need and may reduce the time to a medicine's approval or to its reimbursement for targeted patient groups. It involves balancing the importance of timely patient access with the need for adequate, evolving information on a medicine's benefits and risks. The Adaptive Pathways approach builds on regulatory processes already in place within the existing European Union legal framework. F2G Ltd is one of only a small number of companies who have been accepted into this programme and will seek initial approval for F901318, a novel IV and oral, systemic antifungal targeted at Invasive Aspergillosis on the basis of a Phase IIb randomised controlled clinical trial.

Mr Ian Nicholson CEO said "We are delighted to have been accepted into the EMA Adaptive Pathways programme which has the potential to accelerate the approval process for F901318. This will ultimately lead to patients receiving our drug sooner than would normally be the case and will provide treatment options in settings where current choices are inadequate. We would like to thank the EMA and the European HTAs who contributed to the review and collaborative feedback on our proposal at recent EMA/HTA parallel scientific advice."

Mr Nicholson concluded "this has been a tremendous effort by our internal team and external collaborators in order to submit such a detailed proposal to the EMA and we are grateful for the EMA's positive review."

About F2G Ltd

F2G is a world leading UK biotech company focusing on the discovery and development of novel therapies to treat life threatening invasive fungal disease. F2G have discovered and developed a completely new class of antifungal agents called the orotomides. The orotomides are active against Aspergillus and other filamentous moulds and act via a completely different mechanism than currently marketed antifungal agents. This means that orotomides are active against infections resistant to current therapies, a growing problem globally.

PRESS RELEASE



F901318 is the leading member of the orotomide class and is currently completing Phase One Intravenous and Oral clinical trials. Phase Two clinical trials in Invasive Aspergillosis and *Scedosporium prolificans* infections are planned for the end of 2016.

F2G is backed by leading venture capital companies including Advent Life Sciences, Novartis Venture Fund, Sunstone Capital and Merifin Capital.

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