



Quality, Regulatory and Clinical Consultancy

19 July 2017

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)
Fachregistratur Klinische Prüfung
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
Germany

Dear Sir,

Re.: End of Trial Declaration
Sponsor: F2G Ltd
EudraCT No.: 2016-002271-97
Vorlage No.: 4041898
Protocol No.: F901318C21
Protocol Title: An open label phase IIa clinical study to evaluate the safety and pharmacokinetics of oral F901318 (combined with fluconazole and posaconazole) for antifungal prophylaxis in patients undergoing chemotherapy for acute myeloid leukaemia (SAFEGUARD FP)
Product: F901318

On behalf of F2G Ltd, QRC Consultants Ltd (QRCC) is pleased to submit the end of trial declaration for the study detailed above. For business reasons F2G has taken the decision not to proceed with this clinical trial. We can confirm the site was not initiated and therefore no patients were recruited or treated. The decision to not conduct the trial was made on 10 May 2017.

A completed Declaration of the End of Trial Form dated 30 May 2017 is enclosed.

We can confirm that a clinical study report will not be produced and as such, the trial synopsis will not be submitted to the BfArM and no data will be uploaded to the EudraCT database. We will of course inform the BfArM of this formally once we have received acknowledgement of this submission.

I trust that the information provided is satisfactory. However, please contact me should you require any further information.

Yours sincerely,

Sarah Nicholson PhD MTOPRA
Director and Principal Regulatory Consultant

Encs

cc: Dr Anthony Kennedy, Chief Scientific and Development Officer, F2G Ltd

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