Boehringer Ingelheim

Clinical Study Synopsis for Public Disclosure

This clinical study synopsis is provided in line with **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

The synopsis - which is part of the clinical study report - had been prepared in accordance with best practice and applicable legal and regulatory requirements at the time of study completion.

The synopsis may include approved and non-approved uses, doses, formulations, treatment regimens and/or age groups; it has not necessarily been submitted to regulatory authorities.

A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country..

Additional information on this study and the drug concerned may be provided upon request based on **Boehringer Ingelheim's Policy on Transparency and Publication of Clinical Study Data**.

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Other Clinical Report - Statement of subject enrolment

Document Number: c02721273-01

BI Trail No.:	1241.42
EudraCT No.:	2013-000767-88
BI Investigational Product:	Deleobuvir (BI 207127)
Title:	A randomised, assessor-blind, placebo and active controlled, parallel group study to assess the phototoxic potential of Faldaprevir (administered orally, once daily) for 6 days in healthy male and female subjects
Clinical Phase:	1b
GCP Compliance:	Yes
Authors:	[redacted]
Principal/Coord. Investigator:	[redacted]
Institute/ Department:	[redacted]
	Phone [redacted] Fax
Date of Report:	18 July 2014
Dates of Trial:	From 25 April 2014 To 13 June 2014
Additional Reports:	

2. TABLE OF CONTENTS

3. SUMMARY STATEMENT

This trial was designed to look at potential phototoxic reactions in subjects given Faldaprevir. This was set up in a Phase I unit in Edinburgh and all subjects were to be recruited from this one site. Please refer to the clinical trial protocol document number c02240830-12 for details on trial design, objectives and primary endpoint.

Four subjects were enrolled (Screened) into the trial but no subject was entered (randomized):

After the four subjects had been consented and the screening visits conducted there was then a hold put on the trial by the company.

On the 13 June confirmation was sent to the trial team that this trial would be cancelled due to the termination of the Faldaprevir program. The data from this trial was no longer required and so the site was informed on the 13 June 2014 that the trial was cancelled and there would be no further visits for the subjects that were screened. All the subjects were informed of the trial termination.

4. TRIAL DATA

Four subjects were enrolled and signed consent to participate on the trial. All four subjects were recruited at the [redacted]

S501 consented 09/05/14 screened 09/05/14
S502 consented 09/05/14 screened 09/05/14
S503 consented 15/05/14 screened 15/05/14
S504 consented 15/05/14 screened 15/05/14

No adverse events (AEs) were recorded for any of these subjects.