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**.

Other Clinical Report

	Document Number: c11536357-01
BI Trial No.:	1268.4
EudraCT No.:	2009-013040-36
BI Investigational Product:	BI 671800
Title:	Relative bioavailability of different salt forms and different extended release formulations of single doses of either 50 or 200 mg BI 671800 in the fasted or fed state. An open-label, randomised, Phase I study with a 5-way crossover followed by two treatment periods in fixed sequence in healthy male and female volunteers
Clinical Phase:	1
GCP Compliance:	Yes
Authors:	Dr. [redacted]
Principal/Coord. Investigator:	Dr. med. [redacted]
Institute/ Department:	[redacted] Germany
Date of Report:	28 July 2016
Dates of Trial:	From 18 Feb 2010 To 19 Feb 2010
Additional Reports:	

2. TABLE OF CONTENTS

3. INTRODUCTION

This trial was designed to assess the safety, tolerability and PK of different extended release formulations of BI 671800 HEA in healthy volunteers. The study was planned in a Phase I unit in [redacted], Germany and all subjects were to be recruited from this one site. Please refer to the clinical trial protocol document number U09-2518-01 for details on trial design, objectives and primary endpoint.

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

After the 37 subjects had been consented and the screening visits conducted the trial was cancelled on 18-Feb 2010 by the company due to the termination of the extended release formulation program, following information from a separate study (1268.60) demonstrated no absorption of BI 671800 from the colon. The data from this trial was no longer required and so the site was informed on the 18 Feb 2010 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. METHODOLOGY

n/a

5. RESULTS

n/a

6. DISCUSSION

37 subjects were enrolled and signed consent to participate on the trial. All 37 subjects were recruited at [redacted]. The trial was terminated prior to randomization of subjects. No subject was administered BI 671800.

7. LITERATURE REFERENCES

7.1 PUBLISHED REFERENCES

None

7.2 UNPUBLISHED REFERENCES

None