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: c13125249-01

BI Trail No.:	1249.7
EudraCT No.:	2011-000935-98
BI Investigational Product:	Olodaterol & BI 54903
Title:	A single dose, placebo-controlled, randomised, double-blind double dummy, 5-way crossover (7 treatments, 5 periods incomplete block), including 24-h pulmonary function tests, pharmacodynamic comparison of olodaterol/BI 54903 fixed dose combination inhalation solutions via Respimat® (including clinical doses of 1.23/363.6 µg, 2.46/363.6 µg and 4.93/363.6 µg) versus free combinations of olodaterol inhalation solutions (0, 2.5 µg, 5 µg and 10 µg) via Respimat® plus BI 54903 inhalation solution (363.6 µg) in patients with asthma.
Clinical Phase:	IIa
GCP Compliance:	Yes
Authors:	Dr. [redacted]
Principal/Coord. Investigator:	PD Dr. [redacted]
Institute/ Department:	[redacted] Germany
Date of Report:	07 October 2016
Dates of Trial:	From 14 Oct 2011 — From 14 Nov 2011
Additional Reports:	not applicable

2. TABLE OF CONTENTS

3. INTRODUCTION

This trial was designed to establish the olodaterol dose in the ethanolic fixed dose combination (FDC) with BI 54903 which is equivalent in bronchodilator effect and systemic exposure to the 5 µg olodaterol reference dose in the aqueous inhalation solution (AIS).

8 subjects were enrolled (screened) into the trial but no subject was entered (randomized).

After the 8 subjects had been consented and the screening visits conducted the trial was cancelled on 11-Nov 2011 by the company due to the termination of the clinical development of BI 54903 and BI 54903 related fixed dose combinations in asthma and chronic obstructive pulmonary disease.

This decision was the result of unexpected regulatory authority feedback. It became clear that the acceptance criteria for registering a new formulation of a marketed compound as mono-treatment as well as in combination had been tightened to an extent that Boehringer Ingelheim concluded that the ongoing clinical programs would not lead to registration.

4. METHODOLOGY

n/a

5. RESULTS

n/a

6. DISCUSSION

8 subjects were enrolled and signed consent to participate in the trial. The trial was terminated prior to randomization of subjects. No subject was administered BI 54903.

7. LITERATRURE REFERENCES

7.1 PUBLISHED REFERENCES

None

7.2 UNPUBLISHED REFERENCES

None