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***.

SYNOPSIS

Name of company: Boehringer Ingelheim		**Tabulated Trial Report**		Boehringer Ingelheim
Name of finished product: Mobic® Injection		**EudraCT No.:**		
Name of active ingredient: Meloxicam		**Page:**	**Number:**	**Synopsis No.:**
Ref. to Documentation:	**Module:**	**Volume:**		
Report date: 09 February 2010	**Trial No. / U No.:** 107.270/ U10-3293-01	**Date of trial:** 07 Mar 2004 ~ 06 Aug 2005		**Date of revision** (if applicable)**:**

Title of trial:	Post Marketing Surveillance to assess the safety and efficacy of Mobic® (meloxicam) intramuscular injection (7.5mg ~ 15mg, q.d.) up to 3 days (in case of need for prolonged treatment, switch to Mobic® capsule therapy was possible) in Korean patients with osteoarthritis and rheumatoid arthritis (KFDA regulatory requirement PMS)
Principal/Coordinating Investigator:	[redacted]
Trial sites:	Multicenter study (1 country, 41 sites)
Publication (reference):	NA
Clinical phase:	Ⅳ (Local regulatory post-marketing observational study)
Objectives:	The main objective of this PMS study was to monitor and assess the safety of Mobic® intramuscular injection (7.5mg ~ 15mg, q.d.) up to 3 days (in case of need for prolonged treatment, switch to Mobic® capsule therapy was possible) in Korean patients with osteoarthritis and rheumatoid arthritis.
Methodology:	Multi-centre, prospective, observational post-marketing surveillance as required by Korean regulations
No. of patients:	
planne d:	600
act ual:	enrolled: 432 eligible for tolerability and safety assessment: 425 eligible for efficacy assessment: 421
Diagnosis and main criteria for inclusion:	1) Male and female in/ out patients diagnosed with osteoarthritis and rheumatoid arthritis 2) Patient without prior experience with Mobic® injection

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Test product:	Mobic® (Meloxicam) Injection
dose :	7.5mg ~ 15mg
mode of admin.:	Intramuscular injection
batch no.:	NA
Reference therapy:	NA
dose :	
mode of admin.:	
batch no.:	
Duration of treatment:	Up to 3 days (in case of need for prolonged treatment, switch to Mobic® capsule therapy was possible)
Criteria for evaluation:	
Efficac y:	- Efficacy assessment by the treating physician based on 3 categories: 1. Cured* 2. Improved 3. Failed *Cured means "well controlled symptoms" in this study.
Sa fety:	- In cidence, type, on set date, sev erity, actio n tak en, ou tcome, cau sal relationship of adverse events during and after the administration of Mobic® injection
Efficacy & Safety:	- C ombined a ssessment of efficacy, sa fety and t olerability by the t reating physician based on 3 categories: 1. Satisfied 2. Fair 3. Not satisfied
Statistical methods:	Descriptive

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SUMMARY – CONCLUSIONS:

Efficac y:

A total of 432 Case Report Forms were retrieved from 41 study centers. Four hundred twenty five patients were eligible for the tolerability and safety assessment, and 421 patients were qualified for the efficacy assessment.

In the analysis of efficacy, 18% (77/421) were cured, 81% (341/421) were improved and only 1% (3/421) were failed. The efficacy rate was 99% (418/421).

Sa fety:

During t his P MS st udy pe riod, o nly 1 ad verse e vent (p ruritus) was r eported (1/425, 0.2%).

Efficacy & Safety:

Combined assessm ent of e fficacy, safety and t olerability by th e treatin g physician:
- 78% (331/425) satisfied
- 22% (92/425) fair
- only 1% (2/425) not satisfied

Conclusion s:

This PMS study was discontinued beca use the re gistration of M obic® injection was voluntarily withdrawn in Korea for commercial reasons on 16 January 2008. However based on the assessment of collected data (432 patients), it is reasonable to con clude that Mo bic® injectio n (7.5mg ~ 1 5mg, q.d.) is a well to lerated and effective treat ment in patients with osteoarthritis and rh eumatoid arthritis within the Korean setting.