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***.

U07-3089

CLINICAL TRIAL REPORT SUMMARY

Name of company: Boehringer Ingelheim International Trading(Shanghai) Co., Ltd. **Name of finished product:** Micardis® **Name of active ingredient:** telmisartan		**Tabulated Study Report**	
Protocol date:	Trial number: 502.365	**Planned Study period:**	June, 2000—August, 2001
Title of study: 12 week, multi-center, randomized, double-blind, double dummy, parallel group trial comparing the efficacy and safety of 40 & 80 mg telmisartan and 50 & 100 mg Losartan in the treatment of 150 pairs of primary hypertension patients.			
Principal Investigators: [redacted]			
Study centre(s):	7		
Publication:	no		
Clinical phase:	IIIb		
Objectives:	Using Losartan as a comparator, to evaluate the efficacy and safety of telmisartan in the treatment of the mild to moderate primary hypertension patients in China.		
Methodology:	Randomized, double-blind, double dummy, parallel group		
No. of subjects **total:** **each treatment:**	300		
Diagnosis and main criteria for inclusion:	Mild to moderate primary hypertension, the mean sitting valley value of diastolic blood pressure(DBP)≧95 and <110mmHg, and the mean sitting valley value of systolic blood pressure(SBP)<180 mmHg		
Test product 1: **dose:** **mode of admin.:** **batch no.:**	telmisartan tablets 40 mg 80mg oral administration		
Duration of treatment:	12 week		
Reference therapy: **dose:** **mode of admin.:** **batch no.:**	Losartan 50 mg 100mg oral administration		

Criteria for efficacy:	Primary efficacy endpoint: after 8 weeks of treatment, the changes of the mean sitting valley value of DBP(valley value of blood pressure refers to the blood pressure measured prior to the next administration of antihypertensives) Other efficacy endpoints: 1, the changes in sitting valley values of SBP after 8 weeks of treatment; 2, the changes in sitting valley values of DBP and SBP after 4 weeks of treatment; 3, the evaluable cases and its proportions
Criteria for pharmacoeconomics:	

Criteria for safety:	The incidence of adverse events, physical examination, 12 leds ECG, the incidence of clinically significant laboratory abnormalities.
Statistical methods:	Efficacy: the primary efficacy parameters compared was the changes from baseline in the valley values of DBP after treatment for telmisartan and Losartan, the intent-to-treat population(ITT)analyses was employed, the data analyzed included all the patients who at least received one dose of active drug after randomisation, and whose baseline values and the valley values of blood pressure after dosing were effective. The analysis of covariance model was used to analyse the influence of different hospitals, treatments and baseline blood pressure to the valley values of sitting blood pressure. Safety: safety was obtained from the incidence of adverse events of the two treatment groups, Fisher's exact test was used, the statistical significance level was determined as $P<0.05$

Summary conclusion:	Efficacy 1, by the end of 8 weeks after treatment, the sitting valley values of DBP of the patients of both telmisartan group and Losartan group decrease significantly, the decrease magnitude of telmisartan group is slightly greater than that of Losartan group (10.9mmHg vs. 9.3mmHg), but is not statistically significant; 2, the results of analysis of covariance show that by the end of 8 weeks after treatment, the adjusted mean DBP decrease magnitudes of both groups are significantly different (P=0.030), telmisartan group's mean DBP decrease magnitude is greater; 3, by the end of 8 weeks after treatment, the decrease magnitude of mean sitting valley value of SBP in telmisartanthe group is greater than that of Losartan group(12.5mmHg vs. 9.4mmHg), the difference is of statistically significance (t test, P=0.0457; Wilcoxon double sample test, P=0.0373); 4, the overall anti-hypertensive effectiveness of telmisartan is 70.1%, which is greater than that of Losartan, 58.7%, the difference is of statistically significance (P=0.02). The anti-hypertensive effectiveness of 40 & 80 mg telmisartan are greater than that of 50 & 100 mg Losartan, respectively. the difference is of statistically significance (40mg vs. 50mg: 46.3% vs. 32.5%, P=0.010;80mg vs. 100mg: 79.3% vs. 65.3%, P=0.008); 5, the proportions of patients treated with higher doses treatment (telmisartan80mg or Losartan100mg) are significantly different (P=0.011). The proportion of Losartan group is higher than that of telmisartan group (56% vs. 42.1%); 6, by the end of 4 weeks after treatment, there is no significant difference in the magnitudes of the decrease of both the sitting valley value of DBP and the sitting valley value of SBP between the two groups; Safety: The incidence of adverse events of the two groups are similar (telmisartan group 23.2%, Losartan group 22.9%, P=0.952).The most commonly reported adverse events are dizziness, headache and diarrhea, most of them are mild, and can be alleviated rapidly. The results of the study demonstrate that the treatment of mild to moderate hypertension with telmisartan 40mg～80mg, orally administrated once daily, is safe and effective.