SYNOPSIS

Name of Sponsor/Company	Daiichi Sankyo Co., Ltd.
Name of Finished Product	Aodan
Name of Active Ingredient	Olmesartan Medoxomil
Title of Study	An Open Label, Non-comparative Study to Evaluate the Efficacy and Safety of Olmesartan Medoxomil Tablet 20mg in the Treatment of Mild to Moderate Essential Hypertension for 24 Weeks in Chinese Patients & a Sub-group of ABPM Study to Measure the Ambulatory Blood Pressure Change
Investigators	Jun-Ren Zhu
Study Centre(s)	Zhogshan Hospital, Fudan University, total 16 sites in China
Publication (reference)	・ Clinical Drug Investigation (2012) 32:729-734 ・ Blood Pressure Monitoring (2012)17(5):193–197 ・ European Review for Medical and Pharmacological Sciences (2012) 16: 653-659
Studied Period	Dec 2008 - Jan 2010
Phase of Development	Phase IV
Objectives	To confirm the efficacy and safety of Olmesartan Medoxomil 20mg once daily in the treatment of mild to moderate hypertension for 24 weeks in Chinese patients
Methodology	multi-center, open label, single arm, non-comparative study
Number of Patients (planned and analyzed)	Planned: 360 Analyzed: 357
Diagnosis and Main Criteria for Inclusion	Mild to moderate essential hypertension patients, 90<=DBP<110mmHg, SBP<180mmHg, 18years old or more 75years old or less, male/female
Test Product, Dose and Mode of Administration, Batch Number	20mg once daily, and titrate up to 40mg/day when necessary
Duration of Treatment	24 weeks
Reference Therapy, Dose and Mode of Administration, Batch Number	none
Criteria for Evaluation	DBP and SBP changes at clinic, home and by ABPM* from baseline at week 4, 8, 12, 16, 20, 24 after treatment (*: only at 24th week)
Statistical Method	T test, x^2 test, ANOVA

Summary - Conclusion	SBP and DBP at clinic, home and by ABPM were significantly decreased after 24 weeks treatment comparing with before treatment. Each mean SBP/DBP decrement ± SD are as below, Clinic BP：21.2±14.2/16.0±8.8mmHg、 Home BP：17.7±13.1/12.1±7.9 mmHg、 Mean 24 hrs BP: 13.3±16.3/7.6±9.5mmHg Serious adverse events were reported in 7 cases. The safety profile was same as previous reports. Tolerability of olmesartan 24 weeks treatment was confirmed.
Date of Report	10th Jan 2013