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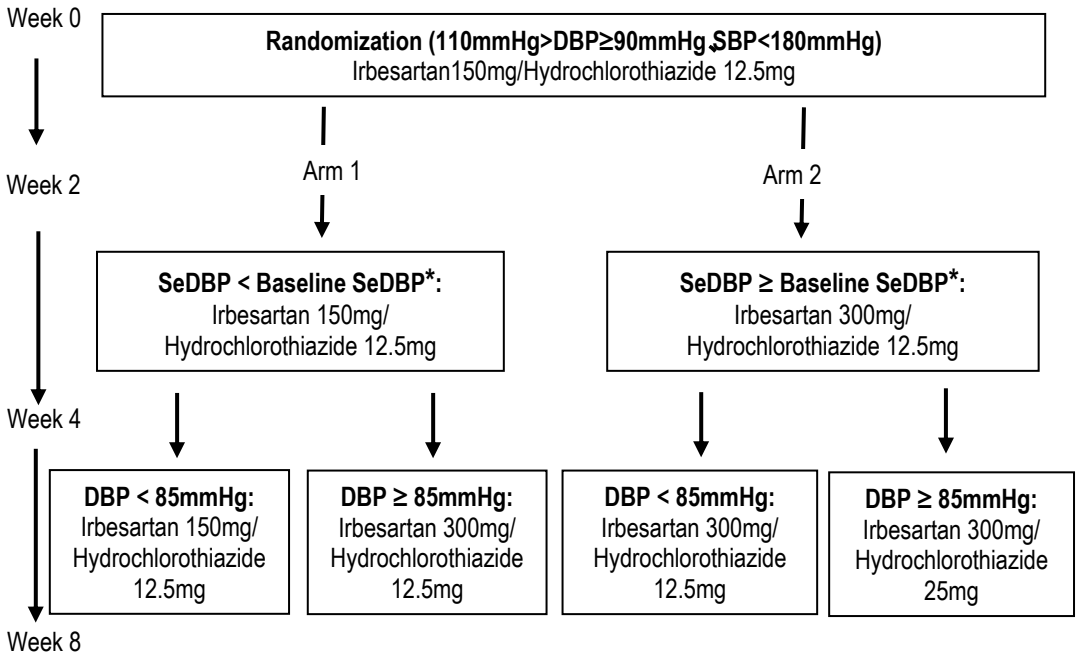
Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00847834
		Study Code:	L_9292
Generic drug name:	irbesartan / hydrochlorothiazide	**Date:**	16 February 2009

Title of the study:	The control rate of irbesartan / hydrochlorothiazide fixed combination in the treatment of Chinese patients with mild to moderate hypertension (Study Number : CoAprovel L_9292)		
Investigator(s):	Prof Sun Ning-ling Department of Cardiology, People's Hospital of Peking University, Beijing 100044, China		
Study center(s):	32 centers , China		
Publications (reference):	Chin J Cardiol, July 2005, Vol. 33 No. 7		
Study period: Date first **patient/subject** enrolled: 22-12-2003 Date last **patient/subject** completed: 20-06-2004		**Phase of development:** Phase IV	
Objectives:	To analyse the control rate of irbesartan/hydrochlorothiazide(HCTZ) (COAPROVEL) in the treatment of patients with mild to moderate primary hypertension.		
Methodology:	This is a multi-center, open, single therapy, 8 weeks trial of irbesartan / HCTZ to evaluate the efficacy and safety in patients with mild to moderate primary hypertension.		
Number of patients/subjects:	Planned: 960	Randomized: NA	Treated:968
Evaluated:	Efficacy / Pharmacodynamics:	Safety: 968	Pharmacokinetics:NA
	Efficacy: Intent-to-treat (ITT) Population: 968 patients Per-protocol (PP) Population: 920 patients Drop out- 48 (Reason: AE-26pts,missed follow up-4pts, withdrew consent form-15pts , lack of efficacy-2pts) AEs leading to discontinuation: Dizziness, headache, gastrointestinal reaction and rashes. Safety : Safety population: 968 patients		
Diagnosis and criteria for inclusion:	Enrolled patients aged between 18 to 75 years old with blood pressure criteria of SeSBP<180 mmHg , 90 mmHg ≤SeDBP<110 mmHg All the patients consent forms were obtained.		

Investigational product:	Irbesartan /Hydrochlorothiazide
Dose:	 * Baseline SeDBP: SeDBP measured when patient was enrolled into the study and before taking first dose of study medication.
Administration:	Oral
Duration of treatment: 8 Weeks	**Duration of observation:** 8 weeks after first dose of study medication
Reference therapy:	NA
Criteria for evaluation:	
Efficacy: Or Pharmacodynamics:	Proportion of patient who reach target blood pressure at 2, 4 and 8 weeks. Target blood pressure was defined as seated diastolic blood pressure < 85 mmHg.
Safety:	Adverse events reported by the patient or noted by the investigator, Standard hematology and blood chemistry, vital signs, physical examination during the follow up period.
Pharmacokinetics:	NA
Pharmacokinetic sampling times and bioanalytical methods:	NA
Statistical methods:	- Analysis of proportion of patients achieving target blood pressure (SDBP < 85 mmHg) at week 2, 4, 8 were based on per-protocol (PP) population - Analysis of blood pressure decrease was based on intention to treat (ITT) population. All paired test or Wilcoxon paired Chi-square test and signed-rank test were used. All the statistical analyses were done with SAS software.

Summary:	
Efficacy results: or Pharmacodynamic results:	(1) Baseline SBP and DBP mean values of these patients are 149.26 and 95.23 mmHg respectively. After 2, 4 and 8 weeks of treatment, 526, 703 and 769 patients reached blood pressure target (diastolic blood pressure less than 85 mmHg). The control rates were 57.17%, 76.41% and 83.59%, respectively. (2) After 2 weeks of treatment, irbesartan/HCTZ lowered systolic blood pressure by 15.74 mmHg and diastolic blood pressure by 11.45 mmHg (P<0.01 versus before randomization). After 4 weeks of treatment, the corresponding decreases were 19.57 mmHg and 14.23 mmHg respectively (P<0.01 versus before randomization). After 8 weeks of treatment, the corresponding decreases were 21.97 mmHg and 16.08 mmHg respectively (P<0.01 versus before randomization). (3) Dosage analysis: See table 1 below Table 1

	Patients * ' number	% of PP population
One tablet COAPROVEL150/12.5mg	637	69.2
one tablet COAPROVEL150/12.5mg and one tablet APROVEL150mg	211	23.0
two tablets COAPROVEL150/12.5mg	72	7.8
Total patients	920	

* They are the patients who receive these dosages at 8 weeks and belong to PP population.

Safety results:	65 out of 968 patients (6.71%) experienced drug–related adverse events. A total of 79 events were report as follows: 17(1.76%) patients experienced dizziness 9(0.93%) patients experienced headache 13(1.34%) patients experienced fatigue 8(0.83%) patients experienced Gasrointestinal reaction 8 (0.83%) patients experienced Urine Acid increased 4 (0.41%) patients experienced Hypokalemia 3(0.31%)(0.93%) patients experienced rashes 1(0.01%) patients experienced lower extremities edema The most common reaction was dizziness with 17 events, and 15 cases were in COAPROVEL150/12.5mg 1 tablet group and only 2 cases in COAPROVEL150/12.5mg 2 tablets group. Dose-dependent adverse reaction was not observed.
Pharmacokinetic results:	NA
Date of report:	December-2008