These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00280605
Generic drug name:	Alfuzosin	**Study Code:**	PM_L_0168
		Date:	23/Jan/2008

Title of the study:	Study of the outcome of patients with lower urinary symptoms suggestive of benign prostatic hyperplasia and treated with alfuzosin 10 mg once daily (Xatral ®XL) for 3 months in China **(ALFONE China)** (PM_L_0168)		
Investigator(s):	Principle Investigator: Prof NA YanQun; LI NingChen Department of Urology, 1st Hospital of Beijing University, No.8, XiShiGu Avenue, Beijing, 10034, China		
Study center(s):	10 centers (in China)		
Publications (reference):			
Study period: **Date first patient/subject enrolled**: 24-Aug-2005 **Date last patient/subject completed**: 05-Apr-2006		**Phase of development:** Phase IV	
Objectives:	The aim of the study is to collect, under daily practice conditions, clinical data on the safety profile and the efficacy of a new formulation of alfuzosin administered once daily (Xatral® XL) in Chinese patients with lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH).		
Methodology:	an open, non-comparative, multi-centre, observational study for 3-month treatment of alfuzosin 10mg daily		
Number of patients/subjects:	Planned: 198	Randomized: Non	Treated: 3-month treatment of alfuzosin 10mg daily
Evaluated:	Efficacy: I-PSS; Quality of Life score; Max urine flow rate; Residual urine	Safety: Adverse events	Pharmacokinetics: NA
Diagnosis and criteria for inclusion:	-Ambulatory patients suffering from LUTS suggestive of BPH -Signed informed consent to participate in the study		
Investigational product: Dose: Administration:	Alfuzosin 10 mg administered once daily at the end of an evening meal		
Duration of treatment: 90 days		**Duration of observation**: 90 days	
Reference therapy: Dose: Administration:	NA NA NA		

Criteria for evaluation:	
Efficacy:	International Prostate Symptom Score (I-PSS) and Quality of Life score were taken as primary efficacy criteria, maximum urine flow rate and residual urine were secondary efficacy criteria.
Safety:	General clinical safety will be assessed by collection of spontaneously reported adverse events at each visit. Cardiovascular safety will be assessed at each visit by blood pressure and heart rate measurement in sitting position after 10 minutes rest.
Pharmacokinetics:	NA
Pharmacokinetic sampling times and bioanalytical methods:	NA
Statistical methods:	The analysis of the primary (efficacy) criteria will be performed on FAS and PPS populations. To assess changes between D0 and Dend, a student test for matched samples will be performed. I-PSS total score and quality of life index at D0, Dend and the absolute changes between D0 and Dend will be described using the descriptive statistics mean, standard deviation, min, max and n. AE analysis will be performed on exposed patients (SS population) and on adverse events occurring during the study and not present before the administration of the study drug. N (%) patients with at least one AE, N (%) with at least one vasodilatory AE; total number of AE with a recapitulative table of the number and percentage of AE sorted by system organ class (according to WHO art). The distribution of the cardiovascular safety parameters (heart rate, blood pressure) will be given in tables with descriptive statistics (mean, standard deviation, minimum, maximum, N) at D0, Dend and Dend-D0.
Summary:	10mg alfuzosin (Xatral XL®) extended-release tablets, when orally taken once daily, can significantly improve the subjective symptomatic scores of patients with benign prostatic hyperplasia and their quality of life, it can increase the maximum flow rates, and decrease the residue urine volume with good safety profile due to low incidence of adverse events.
Efficacy results: or Pharmacodynamic results:	Dend vs D0: IPSS, mean decrease 7.8 ± 5.07 (from 20.76±6.20 to 12.96±5.62, $p<0.0001$); Quality of life, mean decrease 1.56 ± 1.19 (from 4.01±1.00 to 2.52±1.02, $p<0.0001$); Maximum urine flow rate, mean increase, 3.68 ± 6.01 ml/s (from 11.53±6.54 to 15.36±4.88, $p<0.0001$); Residual urine (in patients with D0 volume >50 ml), mean decrease 47.43 ± 59.05 ml (from 94.08±66.08 to 46.64±85.58, $p<0.0001$)

Safety results:	Safety Set: n=189; Incidence of AE: 12.7% (n=24 patients); SAE 0%; Death 0%; 4.23% patients (n=8) withdrawal due to AE. (visual disorders n=1, dizziness n=2, chest pain n=1, cutaneous events n=2, GI disorders n=2) Overall 30 adverse events reported in 24 patients: vasodilatory-related disorders n=15 events (Dizziness n=14; Tachycardia n=1); GI disorders n=4; cutaneous events n=3; visual disorders n=3; cardiac events (chest pain) n=2; others (mouth dry, asthenia) n=3. No events related to hypotension, postural hypotension, syncope, abnormal ejaculation and erectile dysfunction occurred. No significant difference of heart rate and blood pressure between D0 and Dend.

	N	mean	SD	median	min	max
Heart rate (/min) D0	187	77.21	8.08	78	50	76
Dend	172	77.01	7.14	76	58	96
Systolic pressure D0	187	131.98	12.35	130	90	175
(mm Hg) Dend	172	128.52	11.15	130	95	170
Diastolic pressure D0	187	81.02	8.38	80	60	100
(mm Hg) Dend	172	80.00	7.25	80	60	170

.

Pharmacokinetic results:	NA
Date of report:	15-July-2007