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	**ClinicalTrials.gov Identifier:**	NCT00401661
		Study Code:	ALFUS_L_01241
Generic drug name:	Alfuzosin	**Date:**	28 May 2009

Title of the study:	Sexuality And Management of Benign Prostatic Hyperplasia with Alfuzosin 10mg once daily (XATRAL® 10mg OD), open, 24-week study (ALFUS_L_01241)
Investigator(s):	1. Prof.Somboon Leungwattanakit; Urological Center, Bangkok Hospital, Thailand 2. Damrongpan Watanachote.MD.,Ph.D.; Urological Center, Bangkok Hospital, Thailand 3. Assist.Prof.Patranuch Noppakulsatit; Division of Urology, Faculty of Surgery, Thammasat University, Amphur Klongluang, Phathumthani,Thailand 4. Tepchai Petchpaibuol,M.D; Division of Urology, Faculty of Surgery, Thammasat University, Amphur Klongluang ,Phathumthani ,Thailand 5. Assist.Prof.Nopporn Choeypunt; Division of Urology, Department of Surgery, Phramongkutklao Hospital, Bangkok, Thailand 6. Thanasak Tongbai ,MD. ; Division of Urology ,Department of Surgery Buddhachinaraj Hospital, Thailand 7. Teerawan Wanamkang ,MD.; Division of Urology, Department of Surgery, Bhumibol Adulyadej Hospital, Thailand 8. Assoc.Prof.Bannakij Lojanapiwat; Department of Surgery, Faculty of Medicine, Chiangmai University, Chiangmai, Thailand 9. Sompol Permpongkosol, MD, Ph.D.; Division of Urology, Department of Surgery, Ramathibodi Hospital, Mahidol University, Bangkok,Thailand. 10. Assoc.Prof.Anupan Tantiwong; Division of Urology, Department of Surgery, Mahidol University ,Siriraj Hospital , Bangkok, Thailand 11. Assist.Prof.Choosak Pripatnanont; Division of Urology, Department of Surgery,Prince of Songkla University, Hat Yai,Songkla, Thailand 12. Danaipand Akarasakul,M.D. ; Division of Urology, Department of Surgery Rajvithi Hospital, Thailand 13. Somsak Kongwiwatanakul,MD; Urological Center, Department of Surgery, Chonburi Hospital ,Thailand 14. Ekkarin Chotikawanich,M.D.; Division of Urology, Department of Surgery Srinagarind Hospital, Khonkaen University, Thailand

Study center(s):	12 centers in Thailand		
Publications (reference):	LUKACS B., GRANGE J.C. et al. One-year follow-up of 2829 patients with moderate to severe lower urinary tract symptoms treated with alfuzosin in general practice according to IPSS and a health-related quality of life questionnaire. Urology, 2000; 55: 540-546.		
Study period: Date first patient enrolled: 26-Jun- 2006 Date last patient completed: 27-Dec-2007		Phase of development: Phase IV	
Objectives:	Primary objective: To assess the sexual function improvement from baseline to the end of treatment [Week 24 or premature withdrawal (PW)] with XATRAL® 10mg OD. Secondary objective : ▪ To evaluate the association between LUTS severity and sexual disorders, ▪ To assess the onset of action of XATRAL® 10mg OD. ▪ To assess the improvement in urinary symptoms and Quality of Life with XATRAL® 10mg OD. ▪ To assess the safety and the tolerability of XATRAL® 10mg OD.		
Methodology:	Open, non-comparative, multi-centre study.		
Number of patients/subjects	Planned: 110	Randomized: N/A	Treated: 99
Evaluated:	Efficacy : ▪ MSHQ (at baseline, week 4, week 12, week 24) ▪ I-PSS including the Quality of Life index (at baseline, week 1, week 4, week 12 and week 24)	Safety: ▪ Adverse Events reporting during the study. Cardiovascular safety: blood pressure (systolic and diastolic), heart rate at week 4, week 12 and week 24.	
Diagnosis and criteria for inclusion:	Male patients aged ≥ 50 years, suffering from moderate to severe lower urinary tract symptoms (LUTS), suggestive of symptomatic Benign Prostatic Hyperplasia (BPH), with an I-PSS total score ≥ 8, sexually active and having given their written informed consent.		
Investigational product: Dose: Administration:	Alfuzosin 10 mg OD Alfuzosin 10 mg one tablet once daily, at the end of evening meal, prescribed during 24 weeks		
Duration of treatment: 24 weeks		Duration of observation: 24 weeks	

Reference therapy:	NA
Criteria for evaluation:	Efficacy Primary: Mean change from baseline to the end of treatment in the MSHQ Ejaculation score. Secondary: - Mean change from baseline to 4 and 12 weeks of treatment in MSHQ Ejaculation score - Mean change from baseline to 4, 12 and 24 weeks of treatment in MSHQ ejaculation questions, in the erection and satisfaction sub-scores, in the I-PSS total score and in the Quality of Life, in IPSS sub-scores for voiding, filling and nocturia symptoms - Mean change from baseline to week 1 in I-PSS total score and sub-scores - Onset of action based on patient perception - Percentage of patients with a IPSS total score decrease $\geq$ 3 points and increase $\geq$ 4 points - Risk factors and percentage of patients with AUR or BPH surgery - Correlation between MSHQ and IPSS - Evaluation of adverse events, vital signs (blood pressure and heart rate) Safety Evaluation of: - adverse event reports - vital signs (blood pressure and heart rate)
Statistical methods:	Primary efficacy analysis The primary analysis will evaluate the impact of treatment on sexual function based on the mean change in MSHQ Ejaculation score from baseline to study end (week 24 or PW). The proportion of patients presenting an improvement in MSHQ Ejaculation score of at least 20% at study end (week 24 or PW) will be presented with its 95% confidence interval. Secondary efficacy analysis MSHQ: Descriptive statistics for the percentage change and raw differences from baseline in MSHQ Ejaculation score and questions and other sub-scores will be presented after 4, 12 and 24 weeks of treatment. Safety analysis Analyses on laboratory parameters and vital signs were based on the definitions of potential clinically significant abnormalities (PCSA).

Summary:	After 24-week administration of Alfuzosin 10 mg OD, There was an improvement of MHSQ ejaculation score 21.54 vs 23.09 (p=0.022) The proportion of patients presenting an improvement in MSHQ Ejaculation score at least 20% at study end (week 24 or PW) was 27.83% (95% confidence interval: 19.45 – 37.17) There was no strong association between LUTS severity and sexual disorders demonstrated Pearson Correlation analysis demonstrated weak correlation between IPSS and MHSQ. Ejaculation score vs IPSS obstructive at (r^2= -0.261, p=008) Ejaculation bother score vs IPSS obstructive (r^2= -0.202, p=0.041) Premature withdrawal vs IPSS obstructive (r^2= -.0267,p= 0.006) Ninety one cases (91.92%) perceived an improvement of urinary symptom within one month administration. Seventy cases (70.70%) showed an improvement within a week whereas 36 cases (36.36%) improved within 3 days. Improvement in LUTS and QoL was demonstrated by comparing baseline IPSS versus 24th Week IPSS IPSS Total score : 18.93 vs. 9.59 (p< 0.001) IPSS Obstructive score : 11.63 vs. 5.12 (p<0.001) IPSS Irritative score : 7.30 vs. 4.36 (p<0.001) QoL : 4.32 vs. 2.38 (p<0.001) 71 cases (89.9%) was reported a decrease IPSS total score of ≥ 3 Among 99 patients, fifteen adverse events (15.15%) were reported in 13 cases; Dizziness 3 cases; Back pain 3 cases; Acute urinary retention – 1case; Herpes zoster 1 case; Colitis 1 case; Orthostatic hypotension 1 case; Burning sensation at tongue 1 case; Non-ST elevation myocardial infarction 1 case; GI disturbance 1 case; High PSA 1 patient and Fracture left thumb 1 case. There were 4 adverse events related to study drug including 1 case of orthostatic hypotension and 3 cases of dizziness. There was no significant change in blood pressure and heart rate comparing at base line to the end of the study. No treatment discontinuation because of adverse event. No serious adverse event was observed.
Date of report:	31-Mar-2009