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:** NCT00359229
	Study Code: ZOLPI_L_01540
Generic drug name: Zolpidem	**Date:** 02 October 2008

Title of the study:	Stilnox Treatment in elderly patients with insomnia in China		
Investigator(s):	1.Peking University No.6 hospital Dept of Psychiatry :Prof. Xin Yu 2.Peking University Peoples Hospital Dept of Neurology : Prof. Gao Xuguang 3.Beijing Anding Hospital Dept of Psychiatry : Prof. Ma Xin 4.Beijing Union Hospital Dept of Neurology : Prof. Cui Liying 5. Shanghai Mental health center Dept of Psychiatry: Prof. Lu Zheng 6.Guangzhou First Peoples hospital Dept of Neurology : Prof. Pan Xiaoping 7.Shanghai No.1 peoples hospital : Prof. Chen Zhiqing 8.Shanghai No.1 Peoples hospital Branch hospital : Prof. Wang Shaoshi		
Study center(s):	8 centers in China		
Publications (reference):	None		
Study period: Date first patient/subject enrolled: 06-Jul-2006 Date last patient/subject completed: 07-Sep-2007		Phase of development: Phase IV	
Objectives:	Primary: To evaluate the efficacy of Stilnox 5mg after 1 week treatment of primary insomnia in elderly patients in China. Secondary: To demonstrate the improvement in PSQI, period of sleep onset latency, total sleep time after 1 and 3 weeks Stilnox 5mg therapy. Safety outcomes: Safety was assessed by collection of reported adverse events(AEs),routine physical examination, laboratory assessments and changes in HAMA and HAMD from baseline.		
Methodology:	Multicentre, prospective, open label , 3 week trial of 5mg Stilnox® to evaluate the efficacy and safety in elderly patients with insomnia in China		
Number of patients/subjects:	Planned: 180	Randomized: NA	Treated: 115
Evaluated:	Efficacy/Pharmacodynamics:	Safety: 115	Pharmacokinetics: NA

	Efficacy: Intent–to-treat (ITT) Population: 115 patients; Per-protocol(PP) population:75 patients Drop out-31(Reasons: TEAE-11pts,Lack of efficacy-10pts,missed follow up-8pts, withdrew consent form-2pts) TEAEs leading to discontinuation : Mild dizziness, Moderate headache, Mild drowsiness etc Violation of protocol -9pts (stopped previous medication just 1 or 2 days before Stilnox initiation-5pts,non compliance-3pts, <65yrs old-1pt) Safety: Safety population: 115 patients
Diagnosis and criteria for inclusion:	Adults(≥65Yrs) who meet the diagnostic criteria of primary insomnia as defined by the Diagnostic and Statistical Manual of Mental Disorders(DSM-IV), experiencing sleep disturbances at least 3months prior to study entry, total daily sleep time≤6.5hours.
Investigational product: Dose: Administration:	Zolpidem 5mg Nightly Oral
Duration of treatment: 3 weeks	Duration of observation: 3 weeks after first dose of study medication
Reference therapy:	NA
Criteria for evaluation:	
Efficacy: Or Pharmacodynamics:	The primary measure of efficacy was performed through the PSQI survey, sleep variables (including minutes of sleep latency, on an hourly basis of total sleep time), and HAMD, HAMA score on a comprehensive evaluation of insomnia symptoms. Statistical analysis emphasized the change in scores from baseline to the end of treatment(week3).
Safety:	Safety: AEs reported by the patient or noted by the investigator, standard hematology, blood chemistry, vital signs, physical examination during the follow up period.
Pharmacokinetics:	NA
Pharmacokinetic sampling times and bioanalytical methods:	NA

Statistical methods:	The intent-to-treat population (ITT) consist of all treated subjects. If any major protocol violation and/or withdrawal should occur before the subject has completed the study treatment, an analysis will be performed using a per-protocol population (PP), which will consist of all randomized subjects who complete the study according to the protocol without any major protocol violation. Primary objective Variable: The PSQI change from baseline at week 1 Statistical method: Paired t test or Sign rank test (if data is not normally distributed) significance level: 0.05 Secondary objectives 1) The PSQI change from baseline at week 3 2) The change of sleep onset latency from baseline to week 1 or week3 3) The change of total sleep time from baseline to week 1 or week 3 4) The change of HAMD scores from baseline at week 3 5) The change of HAMA scores from baseline at week 3 For above variables, the statistical methods and significance level are same to the primary objective. 6) The change of quality of sleep from baseline to week 1 or week 3 Statistical method: chi square test. Significance level: 0.05

<table>
<tr><td>Summary:</td><td></td></tr>
<tr><td>Efficacy results:
or
Pharmacodynamic results:</td><td>
Main efficacy results (ITT): The results described here are based on the ITT population. The results of the analyses of the ITT and PP populations were very similar :
<table>
<tr><td>Variable</td><td>Week 1</td><td>P</td><td>Week3</td><td>P</td></tr>
<tr><td>Mean change from baseline in PSQI score</td><td>-2.8 (n=115)</td><td><0.0001</td><td>-3.2
(n=93)</td><td><0.0001</td></tr>
<tr><td>Mean change in total sleep time(TST) from baseline.</td><td>87.12 minutes
(n=107)</td><td><0.0001</td><td>100.2 minutes
(n=92)</td><td><0.0001</td></tr>
<tr><td>Mean change in Sleep onset latency from baseline.</td><td>-33.19 minutes
(n=107)</td><td><0.0001</td><td>-39.19 minutes
(n=93)</td><td><0.0001</td></tr>
<tr><td>Mean change in HAM-Anxiety rating score from baseline.</td><td colspan="2"></td><td>-2.1
(n=99)</td><td><0.0001</td></tr>
<tr><td>Mean change in HAM-Depression rating score from baseline.</td><td colspan="2"></td><td>2.7
(n=99)</td><td><0.0001</td></tr>
</table>
The Stilnox treatment had significantly improved Pittsburg Sleep Quality Index(PSQI), Total Sleep Time(TST) and all other sleep characteristics with respect to baseline scores. These differences were statistically significant at all visits at the end of 1st and 3rd week of treatment.

Mean PSQI scores also improved in two sub-groups, consist of elderly patients with high blood pressure and diabetes and non hypertensive and non diabetes group.

The HAM-Depression and HAM-Anxiety rating score showed significant improvement after Stilnox therapy at week 3.

Improvement was observed on the following secondary sleep related variables after Stilnox treatment:
- Rating of sleep quality
- Impact of sleep on daily activities
- Number of awakenings
- Sleep latency, total sleep time etc
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<tr><td>Safety results:</td><td>Safety results:

<table><tr><td>Type of event (N=115)</td><td>N(%)</td></tr><tr><td>Patients with any TEAE</td><td>17(14.8%)</td></tr><tr><td>Patients with serious TEAEs</td><td>1(0.9%)</td></tr><tr><td>Deaths</td><td>0(0)</td></tr><tr><td>Patients with TEAEs leading to discontinuation of investigational product</td><td>11(9.6%)</td></tr></table>
Stilnox was generally well tolerated in this study. The nature, frequency and intensity of TEAEs were within acceptable limits. The most frequently reported TEAEs that occurred during treatment were dizziness, headache and drowsiness.

Laboratory values,vital signs and physical examination findings revealed no meaningful changes or clinically relevant differences from baseline characteristics.</td></tr>
<tr><td>Date of report:</td><td>14-Aug-2008</td></tr>
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