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Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00292734
		Study Code:	L_9259
Generic drug name:	Zolpidem	**Date:**	04/Dec/2007

Title of the study:	**Adjuvant Zolpidem therapy in the treatment of insomnia in patients with dysthymic or depressive disorders treated with recently started antidepressants (_9259)**		
Investigator(s):	**Maria Varszegi, MD, PhD** Center of Sleep-Diagnosis and Therapy Specialist Medical Care of Local Government of Szeged		
Study center(s):	5 - Hungary		
Publications (reference):	No		
Study period: **Date first patient/subject enrolled:** 15-Jan-2005 **Date last patient/subject completed:** 24-Jan-2006		**Phase of development:** Phase IV	
Objectives:	Phase IV study was conducted to evaluate whether the adjunctive zolpidem therapy would enhance the effectiveness of the antidepressant therapy in the treatment of secondary insomnia during the acute phase of dysthymic and mild to moderate depressive disorder		
Methodology:	Open-label, randomized, multicentric, parallel-group (antidepressant+zolpidem vs. antidepressant in itself), prospective study		
Number of patients:	**Planned**: 120	**Randomized**: 125	**Treated:** 115
Evaluated:	**Efficacy**: The degree of insomnia and the quality of relaxedness after awakening - based on insomnia questionnaires	**Safety**: adverse event reporting	**Pharmacokinetics**: No
	(1) Mean number of nights per week when spent awake more than 1 hour after falling asleep (2) Time spent in bed during last two weeks (3) Impairment of normal daily function, job productivity during last days (4) Duration between the lights out and falling asleep last night (minutes) (5) Mean number of night awakenings during last week (6) Duration of sleep (hours) (7) Duration between the awakening and the getting up (minutes) (8) Quality of sleep (9) Relaxedness in this morning (10) Concentration in this morning (11) Sleepiness in this morning		
Diagnosis and criteria for inclusion:	Female/male, in-/out-patients between 18-75 years with secondary insomnia due to dysthymic or mild to moderate depressive disorder (DSM-IV) treated with SSRI not longer than a week. BDI, written informed consent.		

Investigational product: Dose: Administration:	Zolpidem tartrate 10 mg oral
Duration of treatment: 2 weeks	**Duration of observation:** 2 weeks
Reference therapy: Dose: Administration:	No NA NA
Criteria for evaluation:	
Efficacy:	The degree of insomnia and the quality of relaxedness after awakening (based on insomnia questionnaires)
Safety:	Adverse events reported by the patient or noted by the investigator
Statistical methods:	Routine descriptive statistics
Summary:	The insomnia in patients with depressive disorder can improve sooner with adjunctive zolpidem therapy applied during the early phase of depressive episode. There was no difference in reported adverse events between the (with or without zolpidem) treatment groups.
Efficacy results:	At the study entry the demographic (gender, age) and the physical parameters (weight, height, blood pressure, and heart rate), the severity of insomnia (questionnaire), the severity of depression (DSM, BDI) and the type of antidepressant therapy didn't differ in the two study groups. At the end of the study there were significant differences in the improvement of insomnia between the study groups on the basis of insomnia questionnaire. In the group treated with adjunvant zolpidem therapy the mean number of nights per week when spent awake more than 1 hour after falling asleep were decreased (at the end of study with zolpidem: 3 nights =: N=49, 3-5 nights: N=6, and 6-7 nights: N=2 persons; without zolpidem: 3 nights =: N=33, 3-5 nights: N=23, and 6-7 nights: N=2 persons; *p*=0.0008, two-sided, Fischer's exact test) and the impairment of normal daily function decreased (at the end of study with zolpidem: none: N=21, mild: N=27, moderate: N=7, marked: N=1, couldn't work: N=0 person; without zolpidem: none: N=10, mild: N=17, moderate: N=25, marked: N=6, couldn't work: N=0 person; *p*=0.0068, chi-square). At the end of the study on the basis of the sleep diary in the patients treated with add on zolpidem therapy the sleep latency decreased (with zolpidem the latency: < 30 minutes: N=24, > 30 minutes: N=16 persons; without zolpidem: < 30 minutes: N=13, > 30 minutes: N=28 persons; *p*=0.0143, two-sided, Fischer's exact test).
Safety results:	There were no withdrawal of consent due to AE, the causes of all drop out cases (N=10) were protocol violations. During the study there were no significant differences in the rate of reported adverse events between the study groups. In the zolpidem group 2 persons, in the antidepressant in it group 3 persons reported adverse events. One of the patients with zolpidem therapy had nausea and anxiety, the other had headache. There were no reported serious adverse events during the study. The patients treated with adjuvant zolpidem therapy judged their treatment better (with zolpidem: excellent: N=9, good: N=24, weak: N=7, bad: N=0 person; without zolpidem: excellent: N=4, good: N=8, weak: N=12, bad: N=1 person; p=0.0054, two-sided, Fischer's exact test), they were more satisfied with it (with zolpidem: very satisfied: N=25, satisfied: N=25, slightly satisfied: N=5, unsatisfied: N=2 persons; without zolpidem: very satisfied: N=14, satisfied: N=17, slightly satisfied: N=23, unsatisfied: N=4 persons; p=0.0008, chi-square), and they felt it more effective (with zolpidem: effective: N=50, moderate: N=4, ineffective: N=3 persons; without zolpidem: effective: N=26, moderate: N=17, ineffective: N=13 persons; p<0.0001, chi-square) than the patients treated with antidepressants in itself.
Date of report:	19- Sep-2007