Clinical study summary (CSS)

CT registry ID#: NCT00139854
Study no.: SP829

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Proprietary drug name	**INN**	**Therapeutic area and indication(s)**
NIRAVAM	Alprazolam	Anxiety

Name of Sponsor/company: UCB

Title of study:
A multicenter, open-label, randomized crossover trial to assess subject preference for alprazolam orally disintegrating tablets compared to conventional alprazolam tablets in subjects with anxiety.

Investigator(s): 10

Study center(s): 10

Length of study:
Date first patient enrolled: 20 Aug 2004
Date last patient completed: 18 Nov 2004

Phase of development: Phase 3b

Abstract:
This was a multicenter, open-label, randomized crossover trial, comparing 2 treatments, alprazolam orally disintegrating tablets (ODT) vs conventional alprazolam tablets in subjects already taking conventional immediate-release alprazolam tablets for anxiety.

Following a Screening Visit (Visit 1), eligible subjects were randomized 1 week later (at Visit 2) to 1 of 2 treatment schemes: 1 week conventional alprazolam (till Visit 3) followed by 1 week alprazolam ODT (till Visit 4), or 1 week alprazolam ODT (till Visit 3) followed by 1 week conventional alprazolam (till Visit 4). The subjects then resumed taking their conventional treatment. A telephone Follow-Up Visit (Visit 5) was performed 1 week after resuming conventional treatment, to assess the subject's health status.

The primary efficacy measure was the responses to the Subject Preference Questionnaire, questions 1 to 7b (completed at Visit 4). Secondary measures included responses to Subjects' Global Impression Scale and Sheehan Disability Scale (completed at Visit 3 and Visit 4), as well as the investigators' responses to Clinical Global Impression Scales (CGI) for severity of illness (CGI-S) and for improvement (CGI-I) (completed at Visit 3 and Visit 4).

Safety was assessed based on reported adverse events (AEs), concomitant medication usage, physical examination, oral cavity examination, vital signs, and clinical laboratory tests.

Number of subjects:	**Overall**
Planned, N:	60
Randomized, N	61 (100.0)
Completed, n (%):	59 (96.7)
Withdrawn due to adverse events, n (%):	0

Safety outcomes:
- Summary of treatment emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:
No clinically meaningful trend was observed in the reported AEs. No serious AEs were reported and no subjects discontinued due to AEs. The only noteworthy drug-related AE reported was mild to moderate dysgeusia reported in 5 subjects during the study period and in 4 other subjects during the screening period.

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In general, the clinical laboratory test results, vital signs, physical examinations, and oral cavity examination were considered to be within normal limits and/or not clinically significant. Alprazolam ODT had a very similar safety profile to conventional alprazolam.

Treatment-emergent AEs (TEAEs):

Subjects with at least one TEAE, n (%):	**22 (36.1)**	
Subjects with TEAEs	***Conventional alprazolam N=60***	***Alprazolam ODT N=60***
	n (%)	
Any TEAE	9 (15.0)	15 (25.0)
TEAEs considered by investigator as highly probably, probably, or possibly related to drug.	4 (6.7)	5 (8.3)

Death and other SAEs:

Death, n (%):	0
Subjects with SAEs, n (%):	0

Primary & secondary outcomes:

Results based on the subject Preference Questionnaire (question 1) showed that overall, 39.0% preferred alprazolam ODT, 35.6% preferred conventional alprazolam, and 25.4% of subjects had no preference for either formulation. Of those who preferred alprazolam ODT, convenience and quick self-administration were the most frequently cited key reasons.

Based on questions 2 through 7, a statistically significantly larger number of subjects felt the ODT formulation was more convenient to use, more discreet to take, and offered quicker access compared to conventional alprazolam, excluding subjects with no preference. In subjects who took their dose on an as-needed basis, a larger number of subjects found the ODT formulation faster to take and easier to swallow compared with conventional alprazolam, excluding subjects with no preference.

Publication reference(s) based on the study: none

Date of report: 19 Nov 2008