AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel
ACTIVE INGREDIENT: Quetiapine

Study No: NIS-NKR-SER-2007/2
A 8-week, Multicenter, Open-label, Observational Study of the Efficacy of Quetiapine Fumarate (SEROQUEL ^{TM}) Immediate-release Tablets in Adult Patients with Bipolar Depression.

Developmental phase: Marketed
Study Completion Date: 2007-12-28
Date of Report: 2008-10-15

OBJECTIVES:

The primary endpoint of this study was to evaluate efficacy of Quetiapine in adult bipolar depression patients treated with Quetiapine during 8 weeks under actual clinical situation. The secondary endpoint was to evaluate effect of Quetiapine on patient's sleep symptoms during study period and incidence rate of hypo manic/manic conversion (when CGI-BP score is ≥ 3) during study period.

METHODS:

This study was a prospective, observational, non-comparative, 8-week follow-up study conducted under conditions of usual clinical practice. It was a multicenter study conducted between June 2007 and December 2007, in which about 90 psychiatrists from throughout Korea participated.
Patients of both sexes, diagnosed as bipolar depression according to DSM-IV-TR criteria, who are prescribed quetiapine and have given written informed consent was included in the study. Patients with known hypersensitivity to quetiapine or any of its components were excluded. All patients who met the selection criteria described above were included in the study, received non-blinded treatment with quetiapine and were followed for 8 weeks.

RESULTS:

The mean treatment dose of Quetiapine was 315.21 (±229.74)mg at 4 weeks, 337.06 (±229.94)mg at 8 weeks
The result of effect of Quetiapine on bipolar depression, primary endpoint of this study, was as following (Table 1).

Table 1. Clinical global impression-BP version

	CGI score			p-value†	Duncan's Multiple Range Test
	N	Mean	±SD		
Visit1	1193	4.23	±1.03		A
Visit2	1175	3.45	±0.94	<.0001	B
Visit3	1193	2.73	±0.96		C

†ANOVA

There was statistically significant difference in patient's distribution by CGI score in each visit (p< 0.0001, Cochran-mantel-Haenszel test).

The mean score of MADRS's estimating the degree of depressive symptoms was 29.61 in the first visit, 20.21 in the second visit and 13.76 in the third visit. This results show MADRS's gradual decrease (p<0.0001) and improvement of depressive symptoms after medication. In add, MADRS's 10 sub items also showed statistical significance in the score change.

In result of sleep evaluation, both sleep evaluation during night and sleep related status during day was statistically significantly decreased (p<0.0001).

Manic (hypo manic) episode which developed during study is as following.
The number of patients experiencing manic (hypo manic) episode in the second visit were 7 (0.60 %). Among them, 3 patients (0.26 %) were manic episodes, and 4 patients (0.34 %) were hypomanic episodes. In third visit, the number of patients who had manic (hypo manic) episode was 4 (0.34 %). Three patients of them (0.25 %) were manic episodes, and 1 patient (0.08 %) was hypomanic episode. In the relativity of study medication to manic (hypo manic) conversion, the number of patients evaluated as 'Not related' was 4 (0.34%), 'Doubtful' was 2 (0.17%) and 'Possible' was 1 (0.09%), respectively at second visit. At third visit, 'Not related' was 3 (0.25%), of 'doubtful' was 1 patient (0.08%).