AstraZeneca

D1441C09907

SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel™

ACTIVE INGREDIENT: quetiapine

Trial title (number): Westenberg OCD study.

Developmental phase: II, III
First subject recruited: 01 December 2003
Last subject completed: 31 August 2006
Approval Date: 14 May 2003

OBJECTIVES

Primary Objective

To determine whether addition of quetiapine addition to SRIs is superior to SRI treatment alone for non-refractory OCD patients.

METHODS

Eighty-two patients with primary OCD according to DSM-IV criteria were randomly assigned in a 10-week, double-blind trial to receive dosages titrated upward to 300 mg/day of quetiapine to citalopram 60 mg/day, or 60 mg/day of citalopram. None of the patients had been treated with an SRI at maximum dose during at least 12 weeks. Primary efficacy was assessed by the change from baseline on the Yale-Brown obsessive-compulsive scale (Y-BOCS), and response was defined as more than 35% reduction on the Y-BOCS. Depression was rated with the 7-item Hamilton Rating scale for Depression (HAM-D), and anxiety was evaluated with the Hamilton Anxiety Scale (HAM-A).

RESULTS

As measured by the reduction in Y-BOCS scores following an ITT-LOCF analysis, quetiapine addition was superior to placebo. Equally, on the CGI, quetiapine addition was superior to placebo with a mean CGI-improvement score of 2.2 ± 1.2 versus 1.5 ± 1.2. Twenty-four patients (70%) responded in the quetiapine addition group versus 20 (50%) in the placebo group using the 35% Y-BOCS response criterion. The HAM-A and HAM-D did not differ significantly between the two treatment groups. Six patients dropped out in the quetiapine + citalopram group versus in the citalopram + placebo group.

REFERENCES: None