AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel XR
ACTIVE INGREDIENT: quetiapine

Study No: NIS-NHU-SER-2010/1
NCT01202617

Developmental Phase: Marketed use- Non interventional Study
Study Completion Date: 13/10/2011
Date of Report: 25/09/2012

OBJECTIVES: To asses the proportion of patient remaining relapse free during the study period and if there is a relation between the relapses and the affective symptoms.

METHODS: Prospective, multicentre, 6-months observational non-intervention trial -. Inclusion criteria: outpatients with stable schizophrenia, diagnosed upon DSM-IV, aged > 18 yrs and undergoing treatment with extended release quetiapine, signed inform consent. Exclusion criteria were: pregnancy, diabetes mellitus, hepatic disease and cerebro- or cardiovascular disease. Evaluations included symptom severity using the CGI-S, symptom improvement using the CGI-I scale, and affective symptoms using the Raskin scale. This was a per protocol analysis.

RESULTS: There were 1606 patients enrolled, of these 59% were female, the mean age was 45.8 years, and the average duration of illness was 13.6 years.
93% of patients were diagnosed with schizophrenia for at least 2 years.
The average treatment duration with quetiapine was 9.2 months.
Based on CGI-S the percentage of severe ill patients was 32.1 % at baseline and 9.9 % at the end of study, the percentage of moderately ill patients was 48.4% at baseline and was 32.5% at the end of the study. All changes were significant.
The average CGI-S score improved significantly from 4.2 (SD 1.0) to 3.3 (SD 1.19) ($p<0.0001$)– (The median score improved significantly from 4.0 to 3.0.) Based on the CGI-I scale 72.0% of patients improved or very much improved at study end compared to baseline ($p<0, 0001$).

The depressive symptoms based on verbally reported Raskin scale I changed from 2.73 to 1.72 ($p<0.0001$), and behaviour evaluated by Raskin scale II changed from 2.61 to 1.61 ($p<0.0001$), baseline vs study end. Secondary symptoms of depression evaluated by Raskin III changed from 2.52 to 1.61 ($p<0.0001$). The improvement was significant in all subscales.
The average dose of extended release quetiapine was 644.6 mg at baseline and 686.9 mg at the end of study. The dropout rate was 3.4% (n=56). Adverse events were reported in 9% of patients and were consistent with the known adverse-event profile for the drug.

Conclusions: In this study extended release quetiapine was generally well tolerated and was associated with improvements in the overall clinical status and the affective symptoms of Hungarian outpatients with schizophrenia .

Figure 1. Average Clinical Global Impression –Severity (CGI-S) scores on the visits

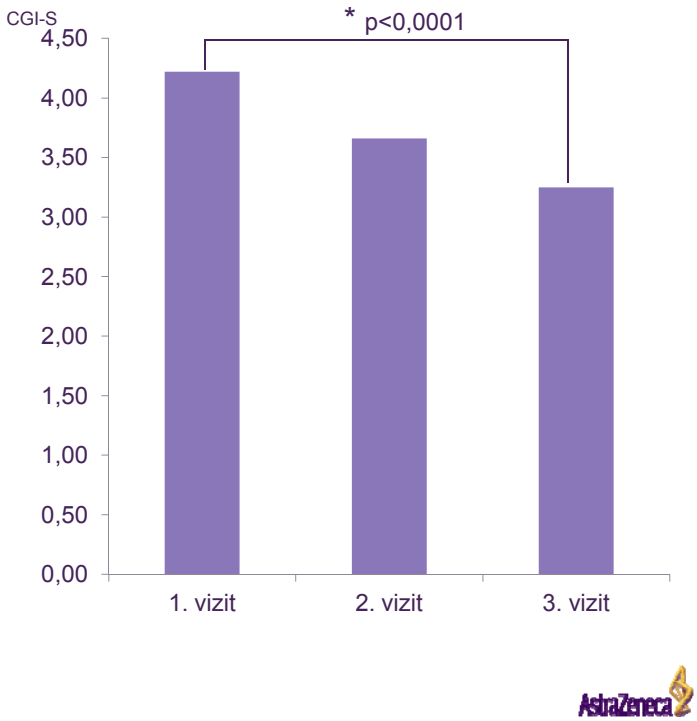

Figure 2. Change of depressive symptoms