ABSTRACT

ASTRAZENECA PHARMACEUTICALS / AstraZeneca Pharma SRL/ Romania

FINISHED PRODUCT: SEROQUEL XR
ACTIVE INGREDIENT: QUETIAPINE XR

Study No: NIS –NRO-SER-2008/1
Non-interventional Study to Assess Treatment Efficacy in Maintaining Symptoms' Control in Patients with Schizophrenia Cured with Seroquel XR (SECURE)

Developmental phase: post marketing, non-interventional observational study
Study Completion Date: July 2009
Date of Abstract: June 2010

OBJECTIVES:

Primary objective:
To assess the efficacy of Seroquel XR treatment in maintaining symptoms'control in schizophrenia over a 6 month observation period.

Secondary objective:
To assess the quality of life, using the Quality of Life Enjoyment & Satisfaction Questionnaire (Q-LES-Q-SF) at the beginning and end of the 6 month study period.

METHODS:

6 month observational study in Romanian patients with schizophrenia, assessed according to usual treatment practice during 7 visits.
Eligible patients were diagnosed with schizophrenia, as per DSM IV TR and have been receiving Seroquel XR for approximately one month before study, as part of their routine treatment. Therapeutic plan, including Seroquel XR and any other medication usage was fully owned by treating phsysician and reflected routine practice. Study protocol included Seroquel XR usage following manufacturer's prescription recommendations. The decisions to modify the treatment (Seroquel XR & associated medication) during the course of the 6-month observation were

subject to the treating physician's usual clinical judgment, with no restrictions imposed by the study protocol.
The study protocol set forth the doctors' responsibility to record the adverse reactions that were spontaneously reported during treatment, according to routine clinical practice.

RESULTS:

578 patients (37% males and 63% females), over 18 years of age, were enrolled.
Over the six month period, there was a significant improvement in symptoms and an average decrease in the BPRS score of 26.3 points: BPRS v1-v7= –26.3 (CI 95% –24.7 - –27.8; p<0.001).
The long-lasting treatment effect is also sustained by the significant decline of symptoms' severity, as illustrated by the CGI-S score evolution, from an average value of 4.7 at baseline to 2.8 after 6 months of treatment: CGI-S v1-v7= –1.9 (CI 95% "1.7 - –2.0, p <0.001). In other words, cases' severity declined, on the average, from "marked" to "mild".
Symptoms have also improved significantly since the observation reference time, with an average variation of CGI-I v2-v7 = –1.1 (CI 95% –1.01 - –1.18, p<0.001).
After the first assessment, "a minimal improvement" of symptoms (modal value 3) was noticed in most patients, an effect consolidated at the end of the study when most patients had a "very high level of improvement" (modal value 1) on CGI-I sub-scale. The mean dose at study entry was 600 mg/day Seroquel XR with a minimum of 200 mg/day and a maximum of 1000 mg/day.

The most frequent adverse reactions that caused the modification of the doses administered in the study population were mainly drowsiness in 0.8% of cases and irritability in 1.03% of cases. In 1.6% of cases, no appropriate therapeutic effect considering the administered doses was noticed.
The remission of adverse events was generally complete upon the following consultation, approximately one month later.

The quality of life, appreciated by patients based on Q-LES-Q SF questionnaire (Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form) improved under all its aspects, especially in a series of items such as: physical health, mood, routine household activities, social relationships, family relationships, daily life functioning, sexual drive / interest / performance, satisfaction with the current treatment.