AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Quetiapine
ACTIVE INGREDIENT:

Study No: CARE I - NIS-NDE-SER-2007/1
CARE I – Evaluation of treatment outcomes in schizophrenic patients taking part in the integrated care program – a single-country, multi-centre non-interventional study

Developmental phase: 4
Study Completion Date: 16.12.2008
Date of Report: 12.10.2009

OBJECTIVES:

Primary objectives

Primary objective was to assess an effect of participation in different integrated care programs on the subjective well-being in patients treated with Seroquel® for symptomatic schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder, or psychotic disorder not otherwise specified. Corresponding primary variable was the mean change in the total SWN score from baseline to final study assessment (i.e., approximately for a 6-month treatment period).

Secondary objectives

Secondary objectives evaluated the influence of Seroquel® with concomitant participation in an integrated care program (ICP) on the following parameters:

1. Subjective well-being using the SWN-K total score
2. Symptomatic outcome using CGI-S and PANSS-8 scales
3. Functional outcome using GAF and Vocational Occupational Index scores
4. Quality of life levels using the Q-LES-Q-18 and EQ-5D questionnaires
5. Compliance/medication adherence using the MARS scale
6. Level of the patients' (subjective) satisfaction using the CSQ-8 scale
7. Health economy improvements in terms of a reduction in treatment costs and loss of productivity by determination of the total number of days with hospitalisation, of days the patient was not able to work or go to school or complete routine daily activities, and of the need for any additional antipsychotic medication
8. Safety and tolerability by evaluation of the incidence of adverse events

METHODS:

Due to the non-interventional character, only an exploratory-descriptive statistical analysis covering all parameters from the CRFs (qualitative, quantitative, text fields with derived and coded variables) was intended for this observation. No formal statistical tests were planned.

Since the study observation period was not extended after December 2008 (which was the initially designed stop date) according to sponsor's decision based on a very slow recruitment with inclusion of only 19 patients so far, it was decided in the final statistical analysis plan of 20 May 2009 that the statistical analyses and evaluations described in the observational plan could not be performed and that merely a synopsis-format CSR would be prepared. No summary tables are provided and no examination of criteria for evaluability (i.e., with respect to the pre-defined analysis sets) was done. Only individual patient data listings primarily for safety data of all documented patients are displayed regarding patient disposition, reason for premature termination, demographic/diagnosis/medication data, and adverse events.

RESULTS:

Summary of efficacy results

The study observation period was not extended to increase the very slow recruitment resulting in only 19 patients of 5 centres (instead of 250 patients planned for 25 centres) as described before according to the sponsor's decision in December 2008 which also was the initially planned stop date defined by the observational plan. Therefore, a relevant amount of efficacy data sufficient for reasonable statistical evaluations, calculations, and analyses could not be collected under consideration of only 19 patients enrolled until stop of the entire project.

Summary of safety results

Until stop of observation a total of 5 adverse events (AEs) were observed in 3 patients. These events were specified as a severe increase of hallucinations with assumed relationship to Seroquel® therapy in one patient, as moderate depressive disorder and moderate hyperhidrosis both without causal relationship to Seroquel® in another patient, and in the third patient as mild chest discomfort without and mild increase of weight with assumed relationship to Seroquel®. Seroquel® treatment was temporarily stopped due to chest discomfort, and it was reduced due to weight increase in this third patient. The events of hyperhidrosis and weight increase had not yet abated before stop of observation in December 2008.

Serious adverse events and discontinuation of observation due to adverse events did not occur in any case.