AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Quetiapine
ACTIVE INGREDIENT:

Study No: D1449L00023
The Effect of the Atypical Antipsychotic Quetiapine in the Treatment of Postpartum Depressive Disorders with or without Psychotic Symptoms

Developmental phase: 2
Study Completion Date: 29.10.2008
Date of Report: 14.09.2009

OBJECTIVES:

Primary objectives

The primary objective of this study was to evaluate the efficacy of quetiapine in the treatment of postpartum depressive disorders in female patients with or without psychotic symptoms. The corresponding primary endpoint was the change in the Hamilton rating scale for depression (HAM-D) from baseline to week 28.

Secondary objectives

To evaluate the effect of quetiapine on depression using the Hamilton rating scale for depression (HAM-D), the Clinical Global Impression (CGI), the Global Assessment of Functioning (GAF), the Montgomery Asberg Depression Rating scale (MADRS), the Brief Psychiatric rating scale (BPRS) and the Parental bonding Questionnaire (PBQ) from baseline to different time points during the study (see study flow chart, table 1) and to week 28.

To determine whether quetiapine is safe and well tolerated as assessed by number and type of adverse events (including clinically significant changes in ECG and occurrence of EPS), changes in vital signs and weight, clinically significant changes in prolactin and oestrogen values and clinically significant changes in laboratory values.

METHODS:

The study has been defined as exploratory and was not powered to address any pre-defined hypothesis. No formal statistical testing was done, descriptive statistics are presented where appropriate. With only 5 patients included summary statistics are only presented for the main efficacy variable.

RESULTS:

Summary of efficacy results

The HAMD total score was reduced in all five patients between baseline and final assessment. The average reduction was 18 +/- 8 points, ranging from 7 to 26 points with a median of 21. At termination four of five patients had an absolute score between 0 to 6 which clinically could be interpreted as remission. The secondary efficacy parameters and patient reported outcomes support the findings on the primary efficacy parameter. Tabulations by patient and time of assessment are available in the appendix. Confidence intervals have been calculated and can be found in the tables. However, there is no reasonable interpretation for such results based on a sample of only five patients.

Summary of safety results

No deaths, serious adverse events or other significant events occurred during this study.

At baseline no concomitant diseases of clinical relevance where reported except for patient [redacted]. Three out of five patients reported non serious adverse events. Patients [redacted] experienced some gastrointestinal problems (nausea, diarrhea, stomach trouble) which were possibly related to trial medication. It should be noted that these two patients received the highest quetiapine dosages realised in this study [redacted] The safety assessments (laboratory, ECG, physical and neurologic examination) did not yield any significant findings. No unexpected safety risks were detected with this study. Besides medication prescribed to treat the medical conditions mentioned the patients received predominantly hypnotics and anxiolytics as a supportive treatment within the allowed ranges as specified by the protocol.

The number and nature of adverse events is within the expected range and does not indicate any so far undetected safety risks.