AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel XR
ACTIVE INGREDIENT: Quetiapine Fumarate extended release

Study No: D1443L00080
RELEASE : A 4-week, Multi-centre, Open-label, Non-comparative, Phase IV Study of the Broad Clinical Benefit for Seroquel XR (Quetiapine Fumarate extended release) with flexible dose as an add-on therapy in the Treatment of Acute Bipolar Mania patients with Partial Response to Current Therapy

Developmental Phase: Phase IV
Study Completion Date: 02-MAR-2011
Date of Report: 27-APR-2011

OBJECTIVES:

The primary objective of this study is to evaluate the broad clinical benefit of dosing Seroquel XR with flexible in the treatment of acute bipolar mania patients with partial response to existing therapy. Clinical benefit will be assessed with the Clinical Global Impression-Clinical Benefit (CGI-CB) score, according to a classification based on the principles outlined in the CGI efficacy index. Improvement in clinical benefit will be defined as a decrease from baseline in CGI-CB.

The secondary objectives of the study are to evaluate the response (greater than or equal to 50% decrease in YMRS Total score), remission (YMRS scores of less than or equal to 12, with a score of less than or equal to 2 on each of the following 4 core YMRS items: irritability, speech, content, disruptive/aggressive behavior) and tolerability of dosing Seroquel XR with flexible dose in the treatment of acute bipolar mania patients with partial response to existing therapy:

- The mean change from baseline to week 4 in YMRS total score
- The CGI-I score change at week 4
- The mean change from baseline to week 4 in CGI-S score
- The mean change from baseline in MADRS total score
- The mean change from baseline in Visual Analogue Scale for Sedation (0-100
- points)
- Reporting Treatment Emergent Adverse Events

METHODS:

This is an 4-week, multi-centre, open-label, non-comparative, phase IV study to evaluate

broad clinical benefit of Seroquel XR with flexible dose in the treatment of acute bipolar mania patients with partial response to existing therapy. After given of written informed consent and undergoing screening procedures, the patients will be assigned to study treatment on Day 1. The effectiveness of Seroquel XR in the treatment of bipolar mania patients will be assessed at Day 29. Patient will not be permitted to use any psychoactive or antipsychotic medications throughout the study period other than those expressively permitted by the protocol.

RESULTS:

Between June 2010 and January 2011, 12 principal investigators recruited 32 patients for treatment of acute bipolar mania using Seroquel XR as add-on therapy. Investigator considers that clinical trials for Seroquel XR in the treatment of bipolar patients are still in infant stage, in particular in Asian countries. In addition, differences in atypical antipsychotic exposure in accordance with race may account for some of variability in response to atypical antipsychotic treatment.

In March 2011, considering the low patient inclusion rate (32 patients recruited so far whereas study objective was 125 patients for 85 completers), the study was ended prematurely earlier than the planned date. No analysis was conducted afterwards.