Summary of non interventional clinical study

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Title: Controll of efficacy and tolerability of Ketilept therapy in acute episodes of schizophrenia and schizoaffective disorder in a multicentre, open, observational study

Objectives. The aim of the study was to assess the efficacy, tolerability and safety of the own developed generic quetiapine, Ketilept® (EGIS Pharmaceutical Ltd, Budapest) in patients with an acute episode of schizophrenia and schizoaffective disorder.

Methods. These was a multicenter, non comparative, open label, 12-week trial on oral generic quetiapine conducted in 110 patients with DSMIV acute schizophrenia or schizoaffective disorder. Patients received Ketilept® 50 mg on day 1, 100 mg on day 2, 200 mg on day 3, 300 mg on day 4. The flexible dosing (150-750 mg/day) started on day 5.

Patients were evaluated at baseline, at day 7, 14, 28 and 84. Baseline and outcome assessment included Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression Severity of Illness Subscale (CGI-S) and Global Improvement Subscale (CGI-I), Subjective Well-being on Neuroleptics Scale (SWN), Simpson-Angus Extrapyramidal Rating Scale (SAS), Barnes Akathisia Rating Scale (BARS) and UKU Side Effects Rating Scale (UKU). Changes in overall body weight, body mass index (BMI) and abdominal circumference were also evaluated.

Results. After 12 weeks on Ketilept® therapy, significant improvements were observed on all major symptoms measures and subscales. 44 (44 %) of patients were rated much or very much improved on CGI-I at week 12. The mean SAS and BARS score significantly reduced during the generic quetiapine treatment period (p=0,0001, p=0,001). No change was found in the body weight, BMI and abdominal circumference during treatment with Ketilept® for 12 weeks. The most common side effects were sedation, and dizziness. 14 adverse events occured in 6 subjects (5%), of whom 3 patients (2,7%) encountered 3 serious adverse events.

The adverse events were mainly mild and moderate.

103 patients (93,6)% completed the study, 2 patients (1,8%) were discontinued from the study due to serious adverse events (insufficient clinical response, sedation).

Conclusion. Despite the limitations of the design, our results suggest that the generic quetiapine, Ketilept® in patients with acute schizophrenia and schizoaffective disorder is therapeutic equivalent to the innovator drug in terms of efficacy, tolerability and safety.