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STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: SEROQUEL®
ACTIVE INGREDIENT: Quetiapine

Study No: BU-5077-0011 (D1441L00028)
A comparative study of quetiapine and risperidone in patients with first-episode psychosis

ABSTRACT:

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PURPOSE:

The benefits of early intervention with optimal treatment of first-episode psychosis are well established. While atypical antipsychotics are known to be an effective first-line therapy for the treatment of first-episode psychosis, there is little information available regarding the relative efficacy and safety of the different atypicals in this population. Here we compare the efficacy and tolerability of quetiapine and risperidone in patients with first-episode psychosis (Study number BU-5077-0011).

METHODS:

We present 8-week interim data from an ongoing 52-week, randomised, rater-blinded, parallel-group study of quetiapine and risperidone in patients experiencing a first episode of schizophreniform psychosis (ICD-10 criteria). Efficacy measures included the Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression – Severity of Illness (CGI-S), Global Assessment of Functioning (GAF), Calgary Depression Scale for Schizophrenia (CDSS) and the Calgary Anxiety Scale for Schizophrenia (CASS). Tolerability was measured using the Antipsychotic Non-Neurological Side Effect Rating Scale (ANNSERS). Patients were assessed at baseline and at 4 and 8 weeks and analysed on a last observation carried forward basis. Patient recruitment is ongoing.

RESULTS:

A total of 69 patients were randomised to treatment. Of these, 33 patients (67% male, mean age 23.7 years) received quetiapine, 34 (80% male, mean age 24.2 years) received risperidone, and 2 refused treatment. The mean rate of patient discontinuation was similar in each group (approximately 8 weeks). The mean (SD) doses at 8 weeks were 420 (174)

mg and 3.3 (1.8) mg for quetiapine and risperidone, respectively. There was no difference between treatments for any of the efficacy assessments. In the overall study population, mean (SD) baseline scores on PANSS positive subscale, CGI and GAF were 17.66 (5.20), 4.94 (0.95) and 33.50 (16.20), respectively. After 8 weeks of treatment, symptoms improved by -5.96, -1.22 and +20.50 on PANSS, CGI-S and GAF, respectively (all $p<0.001$). Furthermore, the overall population showed a non-significant trend towards improvement in depressive symptoms with a change in mean (SD) CDSS score from 5.08 (6.61) at baseline, to 3.31 (4.93) after 8 weeks of treatment ($p=0.054$). There was no significant improvement in PANSS negative subscale scores or CASS scores. Change from baseline in sexual dysfunction was not significant in the quetiapine cohort. The intensity of sexual dysfunction was greater in the risperidone treated patients compared with those receiving quetiapine ($p=0.033$). In the overall population, ANNSERS scores showed that the intensity of problems with sexual arousal were mild; however, the longitudinal increase was significant after 8 weeks of treatment ($p=0.001$). The most common side effects were hyposexuality and difficulty waking in the morning (risperidone and quetiapine groups, respectively). Very low incidences of Parkinsonian extrapyramidal symptoms, akathisia and abnormal movements were reported. All side effects were of mild-to-moderate intensity.