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LONG-TERM TREATMENT WITH AGOMELATINE: PREVENTION OF RELAPSE IN PATIENTS WITH GENERALISED ANXIETY DISORDER OVER 6 MONTHS

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Aim: This study assessed the efficacy of agomelatine (1,2,3), in the prevention of relapse in non-depressed out-patients with DSM-IV-TR defined Generalized Anxiety Disorder (GAD) and the tolerability.

Methods: GAD patients received open label agomelatine (25-50 mg/day). At week 4 the dose was increased for patients with insufficient improvement (blinded criteria). At week 16, responders were randomised to maintenance treatment with either agomelatine, or placebo for a 26 week period. Then, agomelatine treated-patients were re-randomised to an agomelatine arm or to a placebo arm, to confirm the lack of discontinuation symptoms (on the DESS check-list).

The primary outcome was the time to relapse (days) during the 26 week double-blind treatment period, as estimated using the Kaplan-Meier method. Relapse was defined as HAMA total score >= 15 or withdrawal for lack of efficacy (in the investigator's opinion, based on both HAM-A and CGI scores).

Results: 477 patients entered the open-label phase and 329 completed this period. 228 patients were randomly assigned to receive agomelatine (114 patients) or placebo (114 patients).

The incidence over time of relapse was significantly lower with agomelatine compared to placebo (19.7% versus 31.7% log rank test p=0.046) during the double-blind treatment period.

During the double-blind treatment period 12.4% patients with agomelatine and 9.6% with placebo reported at least one emergent adverse event related to the study treatment.

There was no discontinuation syndrome in agomelatine treated patients.

Conclusion: Agomelatine was efficacious in preventing relapse in GAD, with maintenance of efficacy over 6 months, and good tolerability.

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