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SUSTAINED EFFICACY AND SAFETY OF AGOMELATINE 10, 25 AND 25-50MG VERSUS PLACEBO OVER 24 WEEKS IN OUT-PATIENTS SUFFERING FROM MODERATE TO SEVERE MAJOR DEPRESSIVE DISORDER

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The present analysis assesses the 24-week antidepressant efficacy and safety of agomelatine 10, 25 and 25-50 mg versus placebo in out-patients suffering from moderate to severe Major Depressive Disorder (MDD).

In this phase III, international, randomized, double-blind trial, 549 patients were randomized in four parallel groups: agomelatine 10 mg (n=133) , agomelatine 25 mg (n=138), agomelatine 25-50 mg (n=137) or placebo (n=141).

In the FAS (N=547), at last post-baseline assessment, there were significant and incremental differences (E(SE)) on mean HAM-D total score in favor of each agomelatine dose regimen *vs* placebo: 10mg – 4.51(1.06) (p<0.0001); 25mg – 7.74 (1.05) (p< 0.0001); 25-50mg – 7.72 (1.05) (p< 0.0001).

The response rate (decrease in HAM-D total score ≥ 50% from baseline) was higher on each agomelatine group: 63.6% on 10mg, 78.3% on 25 mg, 77.2% on 25-50mg than on placebo group (41.8%), p<0.001, p< 0.0001 and p< 0.0001 respectively.

The remission rate (HAM-D total score<7) was higher on each agomelatine group: 38.6% on 10mg, 55.8% on 25mg and 57.4% on 25-50 mg groups *versus* 22.0% on placebo, p=0.003, p<0.0001, p<0.0001 respectively.

Headache and nausea were the most frequent emergent adverse events on agomelatine irrespective of the dose regimen (in at least 5% of patients).

One patient on agomelatine 10mg, 2 patients on agomelatine 25mg and 2 patients on agomelatine 50 mg versus none on placebo had transaminases increase (>3 ULN). All recovered.

These results show the long-term antidepressant effect over 24 weeks of 3 dose regimens of agomelatine in MDD patients.

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