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EFFICACY AND SAFETY OF 3 AGOMELATINE DOSE REGIMENS (10, 25, 25-50 MG) VERSUS PLACEBO IN OUT-PATIENTS SUFFERING FROM MODERATE TO SEVERE MAJOR DEPRESSIVE DISORDER

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The present analysis assesses the 6-week antidepressant efficacy and safety of 3 agomelatine dose regimens of (10, 25, 25-50 mg) versus placebo in out-patients suffering from moderate to severe Major Depressive Disorder (MDD).
In this phase III, multicentre, international, randomised, double-blind, placebo-controlled trial, 549 patients were randomized in four parallel groups: agomelatine 10 mg (n=133) , agomelatine 25 mg (n=138), agomelatine 25 mg -50 mg (n=137) or placebo (n=141). In the 25-50mg group, a dose up-titration in blinded conditions to 50 mg at week 2 was done if insufficient improvement.
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 *vs* placebo: 10mg - 2.46(0.76) (p=0.001); 25mg - 4.71 (0.75) (p< 0.0001); 25-50mg - 4.92 (0.76) (p< 0.0001).
The response rate (decrease in HAM-D total score ≥ 50% from baseline) was higher on each agomelatine group: 40.9% on 10mg, 50.7% on 25 mg, 52.2% on 25-50mg than on placebo (24.8%), p=0.005, p< 0.0001 and p< 0.0001 respectively.
There were less study discontinuation on agomelatine 10mg, 25mg and 25-50 mg than on placebo (7.5%, 5.8%, 8.0% and 10.6% respectively) and few discontinuations for adverse events (0.8%, 0.7% and 0.7% respectively) *vs* none on placebo.
The most frequent emergent adverse events on agomelatine (in at least 5% of patients in any agomelatine groups) were headache and nausea.
These results demonstrate antidepressant efficacy at 3 dose regimens of agomelatine (10, 25, 25-50 mg) in MDD patients.

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