Article: 3009
Topic: 45 - Depression

RANDOMIZED, DOUBLE-BLIND, STUDY OF VORTIOXETINE VERSUS AGOMELATINE IN ADULTS WITH MDD AFTER INADEQUATE RESPONSE TO SSRI OR SNRI TREATMENT

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Introduction: Vortioxetine (Lu AA21004) is an investigational antidepressant, a multimodal 5-HT_3, 5-HT_7 and 5-HT_{1D} receptor antagonist, 5-HT_{1B} receptor partial agonist, 5-HT_{1A} receptor agonist and inhibitor of the 5-HT transporter.
Objectives: To compare efficacy and tolerability of flexible-dose treatment with vortioxetine versus agomelatine in MDD patients who presented with an inadequate response to SSRI/SNRI monotherapy.
Aims: The primary efficacy endpoint was the change from baseline to Week 8 in MADRS total score analysed by MMRM using a non-inferiority test. Secondary endpoints included assessment of anxiety symptoms (HAM-A), global clinical judgment (CGI), and overall functioning (SDS).
Methods: Randomized, double-blind comparator study (NCT01488071).
Results: Eligible patients were randomized (1:1) to vortioxetine (10-20mg/day) or agomelatine (25-50mg/day) for 12 weeks of double-blind treatment. On the primary efficacy endpoint, vortioxetine (n=252) was statistically significantly superior to agomelatine (n=241) ($p< 0.05$) by 2.2 MADRS points. Significant differences in favour of vortioxetine were found for the MADRS, HAM-A, CGI-S, CGI-I, and SDS from Week 4 onwards (FAS, MMRM; $p< 0.05$) and robustness was confirmed by significant differences by ANCOVA (FAS, LOCF). Fewer patients withdrew due to adverse events with vortioxetine (5.9%) than agomelatine (9.5%). Adverse events with the highest incidence were nausea, headache, dizziness and somnolence.
Conclusions: The primary efficacy endpoint of this comparator study was met, with vortioxetine also showing a significant benefit compared to agomelatine in MDD patients who changed antidepressant after an inadequate response to SSRI/SNRI treatment. Statistically significant differences were seen from Week 4 onwards. This study confirms that vortioxetine is efficacious and well-tolerated.