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Agomelatine as monotherapy for major depression: an outpatient, open-label study

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Vladimir Novotny† passed away on 17 April 2012

Background: Agomelatine is a novel antidepressant agonist to MT1 and MT2 subtypes of melatoninergic receptors (MT1 and MT2) and antagonist to 5-HT_{2C} subtype of serotonergic (5-HT_{2C}) receptors, which has shown antidepressant efficacy in short-term and long-term trials as well as in clinical practice. The purpose of this study was to assess the antidepressant efficacy, safety, and the influence of agomelatine on the functioning of patient in common clinical practice.
Methods: In this open-label, 8-week, multicenter, Phase IV trial, 111 patients with mainly moderate to severe major depressive disorder (39% treatment-naïve) were treated with agomelatine 25–50 mg/day for up to 8 weeks. The primary endpoint was the mean change in total Montgomery and Åsberg Depression Rating Scale (MADRS). Secondary endpoints included assessment of clinical response (defined as a reduction in total MADRS score of ≥50%), and change in Clinical Global Impression scales, Global Assessment of Functioning scale, Sheehan Disability Scale, and CircScreen sleep questionnaire scores. Safety and tolerability were also monitored.
Results: Of the 111 patients enrolled, 94 completed the study. The total MADRS score significantly decreased by the first week of treatment and continued to decline significantly until study completion, with an estimated mean change of 3.9 ± 3.9 and 17.2 ± 8.0 at the first and eighth week of the study (last observation carried forward analyses). All other secondary endpoints significantly improved from early treatment evaluation to study completion. A clinical response was observed in 14.1% of patients after the first week, rising to 74.5% of patients at study completion. There were 31 spontaneously reported adverse events in 17 patients, and most were mild to moderate in severity.
Conclusion: This study showed good short-term efficacy for agomelatine in outpatients with major depressive episodes. Treatment with agomelatine achieved early and consistent responses for symptoms of depression and other dimensions of clinical and functional status. Agomelatine achieved significant improvements in daily functioning of patients, and had good tolerability. Clinically, no hepatic events were observed.

Keywords: agomelatine, monotherapy, depression, remission, functioning

Corrigendum for this paper has been published

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