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THE ANTIDEPRESSANT EFFICACY OF AGOMELATINE IN DAILY PRACTICE: RESULTS OF THE NON-INTERVENTIONAL STUDY VIVALDI*

G. Laux
Department of Psychiatry, Inn-Salzach-Klinikum, Wasserburg a. Inn, Germany

Objective: Agomelatine is a melatonergic agonist and 5-HT_{2C} antagonist with demonstrated antidepressant efficacy in clinical trials. The aim of the non-interventional study VIVALDI was to examine the antidepressant efficacy and tolerability of agomelatine in depressed patients in daily practice.
Methods: 3317 outpatients aged >18 years with first or recurrent depressive episodes were observed by 665 German psychiatrists over 12 weeks. Patients were treated with agomelatine 25-50 mg once daily at bedtime. Antidepressant efficacy was evaluated by the svMADRS (short version MADRS) and CGI scales, effects on sleep and daily activity by a patient questionnaire (CircScreen).
Results: At inclusion, patients showed moderate to severe depression (svMADRS: 0 = 30.6), demonstrating an steady and marked clinical improvement during the 12 weeks of agomelatine treatment (svMADRS: 0 = 12.8). The responder rate (≥50% reduction of svMADRS) rose steadily from 12.3% (2 weeks) to 42.7% (6 weeks) and 65.8% (12 weeks). After 3 months, 54.8% of patients were in remission (svMADRS ≤12). On the CGI scale, 22.8% of patients responded (CGI-I ≤2) after 2 weeks and 72.4% after 12 weeks of treatment with agomelatine. Decrease in repeated and early morning awakenings, and increase daily activities were observed after 12 weeks in 81.5%, 82% and 56.6% of patients, respectively. The tolerability of agomelatine was good.
Conclusion: The antidepressant efficacy of agomelatine on depressive symptoms and daytime activities, as well as its tolerability observed in controlled trials were confirmed by the results of the non-interventional study VIVALDI.
*Valdoxan®: Improves depressive symptoms and normalizes circadian rhythms

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