

P-530 - LONG-TERM ANTIDEPRESSANT TREATMENT WITH AGOMELATINE: RESULTS OF THE NON-INTERVENTIONAL STUDY VIVALDI FOLLOW-UP OVER 12 MONTHS

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Agomelatine is the first melatonergic antidepressant working as MT₁/MT₂-agonist and 5-HT_{2c}-antagonist.

Aim of VIVALDI Follow-up was to examine agomelatine-treatment over one year under routine conditions.

To evaluate the antidepressant effectiveness and tolerability of agomelatine as well as its effects on sleep-wake-rhythms in depressed patients over one year in daily practice.

Optional 9-months-follow-up of the 3-months non-interventional-study VIVALDI. 605 outpatients were observed by 208 psychiatrists over 12 months in Germany and treated with agomelatine 25-50 mg once daily at bedtime. Antidepressant effectiveness was evaluated by svMADRS (short version MADRS) and CGI scales, effects on sleep and daily activity by a patient questionnaire (CircScreen).

At inclusion, patients had a moderate to severe depression (svMADRS total score 30.6), which improved markedly during the 12 months treatment with agomelatine (svMADRS total Score 9.8). The responder rate ($\geq 50\%$ reduction of svMADRS) rose steadily from 15.3% (2 weeks) to 69.7% (12 weeks) and 75.7% (12 months). 59.6% and 69.8% of patients were in remission (svMADRS ≤ 12) after 3 and 12 months, respectively. The CGI-S-Score improved from 4.7 to 2.6 after 12 months-treatment with agomelatine. Improvements in falling asleep and daily activities as well as decrease in repeated awakenings were observed after 12 months by 83.6%, 57% and 87.0% of patients, respectively. Adverse drug reactions (mainly headache, dizziness) were reported by only 4.3% of patients.

Antidepressant effectiveness and good tolerability of agomelatine as well as its marked improvement of sleep-wake-rhythms observed in controlled studies were confirmed by this observational trial in daily psychiatric practice over 12 months.