met screening cut scores for a diagnosis of an anxiety disorder or major depressive disorder. The vast majority felt that cannabis had improved their symptoms and denied symptoms suggestive of cannabis use disorder. Anxiety and depressive symptoms scores were higher in individuals smoking 3 g or more of cannabis per day.

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P.4.d Anxiety disorders, OCD, stress related disorders and treatment – Treatment (clinical)

P.4.d.001 Efficacy and safety of agomelatine 25–50 mg/day versus escitalopram 10–20 mg/day in severe generalized anxiety disorder

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The present analysis assesses the 12-week efficacy and safety of agomelatine 25–50 mg versus escitalopram 10–20 mg in non-depressed outpatients with severe generalized anxiety disorder (GAD).

In this phase III, multicentre, international, randomised, double-blind, comparative trial, 523 patients were randomised into two parallel groups: agomelatine 25–50 mg (n = 261), or escitalopram 10–20 mg (n = 262).

Randomised patients had a mean age of 41 years, and 69% of them were female. All patients fulfilled DSM-IV diagnostic criteria for GAD and experienced functional impairment according to the Sheehan Disability Scale (SDS). The mean HAM-A total score at baseline was 30.3 and did not significantly differ between treatment groups. The mean CGI severity of illness score was 4.9 (markedly ill) and the mean THAT (Toronto Hospital Alertness Test) score was 21.7

In the Full Analysis Set (FAS; N = 519), at week 12, there were incremental decreases on mean HAM-A total score in the agomelatine group – 16.0 ± 9.1 and in the escitalopram group – 16.9 ± 8.4; and the estimated between-group difference (escitalopram minus agomelatine) was E (SE): −0.91 (0.69), 95% CI [−2.26; 0.44]. Based on the predefined non-inferiority margin of 1.5, the non-inferiority of agomelatine compared to escitalopram was not statistically demonstrated; one-sided p-value (to be compared to 0.025) = 0.195, after adjustment for centre (random effect) and baseline HAM-A total score, on the change from baseline to week-12 (using LOCF approach for missing data) (primary analysis).

The response rate (decrease in HAM-A total score ≥50% from baseline) at week-12 (using LOCF approach) was 61% in the agomelatine group and 65% in the escitalopram group.

The patient's alertness as measured by the THAT total score improved over time in each treatment group with similar mean THAT total scores at week 12 (LOCF) of 29.4 ± 10.3 in the agomelatine group and 31.3 ± 9.7 in the escitalopram group.

Fewer patients on agomelatine reported at least one emergent adverse event (EAE) than those receiving escitalopram (46.9% versus 58.8%, respectively).

The most frequent emergent adverse events on agomelatine (reported in at least 3% of patients) were headache (10.4%), nausea (6.5%), fatigue (4.6%), nasopharyngitis (4.2%) and dry mouth (3.8%).

In the escitalopram group, the most frequent emergent adverse events were nausea (17.9% of patients), headache (12.2%), insomnia (6.1%), hyperhidrosis (5.0%), diarrhoea (4.6%), fatigue (4.2%), nasopharyngitis (3.8%), dizziness (3.8%) and anxiety (3.4%).

Overall, 15 patients (5.8%) in the agomelatine group and 22 patients (8.4%) in the escitalopram group reported at least one treatment-related emergent adverse event leading to treatment cessation.

Transaminases increase (ALT and/or AST > 3 ULN) were reported in 2 patients on agomelatine and in 4 patients on escitalopram. All transaminase levels normalised after treatment cessation.

No death occurred during the study.

The symptoms of anxiety improved in both agomelatine and escitalopram groups confirming the efficacy of these treatments in GAD patients. Agomelatine was better tolerated than escitalopram.

P.4.d.002 Evaluating self-knowledge and self-control workshops for patients with anxiety disorders

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Introduction: Anxiety disorders are one the most common psychiatric conditions in the general population. With or without other comorbidities, anxiety disorders are an important health concern and a prevalent reason for primary care visits. Anxiety disorders also involve an extensive use of health resources, regardless of the subject's age, sex and comorbidities [1]. Oliva J et al. [2] estimated that the economic burden of anxiety disorders amounts to 789.4 million Euros per year. The implementation of cost-effective intervention strategies is crucial. A recent review [3]