PW01-23 - **AGOMELATINE, THE FIRST MELATONERGIC ANTIDEPRESSANT: A SUSTAINED EFFICACY IN SEVERELY DEPRESSED PATIENTS**

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Agomelatine is a melatonergic agonist and 5-HT_{2C} antagonist, efficacious in patients with major depressive disorder. The aim of the present analysis was to assess its short- and long-term antidepressant efficacy in the more severely depressed patient according to predefined cut-offs at baseline on HAM-D total score. The short-term treatment efficacy was assessed versus placebo in a pooled analysis from three 6-8 week trials using increasing and non-overlapping cut-offs of the HAM-D_{17} score at inclusion (n=591), and versus fluoxetine 20-40 mg in an 8-week study (HAM-D at inclusion ≥25 and CGI ≥4; n=515). Long-term efficacy was assessed in the severely depressed subpopulation (HAM-D ≥25; n=270) of a relapse prevention study. Agomelatine's doses were 25- 50 mg/d.

In the pooled analysis, the difference between agomelatine and placebo at endpoint increased with increasing severity of depression at baseline, from 2.06 (95% CI, 0.31-3.81; *P*=0.021) (HAMD 22-25) to 4.45 (95% CI, 0.57-8.33; *P*=0.025) (HAMD>30). Agomelatine was significantly superior to fluoxetine, with a difference in the HAM-D score of 1.49 (95% CI, 0.20-2.77; *P*=0.024). Agomelatine was also significantly superior to placebo in preventing relapse in severe depression, with a relapse rate of 21.9% in the agomelatine group versus 45.1% in the placebo group (*p*=0.0001). Tolerability was good in all the studies versus placebo and versus fluoxetine.

In conclusion, these results show that agomelatine is efficacious in severely depressed patients, with a superior efficacy to fluoxetine in the short term. This is in line with the superiority reported of agomelatine versus venlafaxine and sertraline.

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