PW07-01

F2695: A NEW THERAPEUTIC POTENTIAL FOR MAJOR DEPRESSION .A PHASE II DOUBLE-BLIND RANDOMISED TRIAL RESULTS

L. Mansuy

Clinical Research, Pierre Fabre Laboratories, Labège Innopole Cedex, France

F2695 is a novel antidepressant exerts simultaneous noradrenergic and serotoninergic neurotransmitter effects.
F2695 SR was administered in patients with Major Depression in a randomized, multinational, double-blind, placebo-controlled 10-week study, assessing the efficacy and safety of F2695 SR progressive titration safety adapted doses from 75 mg to 100 mg od, in out-patients with Major Depressive Disorders. The 563 randomized patients fulfilled the diagnostic criteria for Major Depressive Disorders and presented moderate or severe Major Depressive Disorders. Efficacy analysis found a significant difference between F2695 and placebo in favour of the active treatment in term of a significantly greater improvement in MADRS total score with F2695 compared with placebo ($p< 0.0001$). In addition, significantly more patients achieved MADRS response (a decrease in total score equal or superior to 50%) and MADRS remission (defined as a total score inferiorior to10) in the F2695 group than in the placebo group such an effect being usually not seen on this measure in the relatively short time span of a ten-week study. At the doses tested, F2695 was effective from early in the treatment (week 2) and the difference in efficacy compared with placebo increased steadily throughout the study.
The severity to entry in this study was relatively high and the mean MADRS entry score was 31, about 40% of patients were in the severe category of depression.
This study: provided evidence of the efficacy of F2695 in major depression population. Therapeutic effect was sustained in term of effect-size, responders and remissions rate, in front of placebo.

https://doi.org/10.1016/S0924-9338(09)70603-0 Published online by Cambridge University Press