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Cariprazine in Negative Symptoms of Schizophrenia: Post-hoc Analyses of a Fixed-dose Phase Iii, Randomized, Double-blind, Placebo- and Active-controlled Trial

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Introduction: Cariprazine, a dopamine D_3/D_2 receptor partial agonist with preferential binding to D_3 receptors, is being developed for the treatment of schizophreni**a**

Objective: To explore the effect of cariprazine on negative symptoms of schizophrenia.

Methods: Subjects aged 18-60 years with acute schizophrenia, current acute episode <2 weeks, and a PANSS total score ≥80 and ≤120 were randomly allocated in a 6-Week study NCT01104766 to cariprazine 3 mg/d, cariprazine 6 mg/d, aripiprazole 10 mg/d (active control), or placebo [1]. Post–hoc analyses were performed on subjects with severe negative symptoms and low-to-moderate positive symptoms, defined according to Marder.

Results of the Post-Hoc Analyses: Data of 26 subjects were included in the cariprazine 3 mg/d (17.2% of the total sample), 34 in the cariprazine 6 mg/d (22.1%), 35 in the aripiprazole (23.3%) and 35 in the placebo (23.5%) groups , respectively. Change from baseline to Week 6 in the PANSS Factor Score for Negative Symptoms (PFSNS) was statistically significant for cariprazine 6 mg/d versus placebo (least squares mean difference: cariprazine 3 mg/d=-2.15, p = 0.20; cariprazine 6 mg/d = -3.68, p=.019). Cariprazine 6 mg/d was superior to placebo at each weekly assessment from Week 3. The changes in PFSNS for aripiprazole were not statistically significant at any weekly assessment.

Conclusion: Post–hoc analyses performed on subjects with acute schizophrenia, high level of negative symptoms and low-to-moderate positive symptoms, showed that the patients in the cariprazine 6 mg/d group had a significantly greater improvement relative to placebo on the PFSNS.
Reference: [1] Lieberman JA, Eur Neuropsychopharm, 2013, 23(Suppl2): S477-S448

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