Article: EPA-0869
Topic: E07 - e-Poster Oral Session 07: Neurobiology, Bipolar Disorders and psychopathology

EFFICACY AND SAFETY OF CARIPRAZINE IN PATIENTS WITH ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER

J.R. Calabrese[1], G.S. Sachs[2], K. Lu[3], M. Debelle[4], **I. Laszlovszky**[4], S. Durgam[5]

[1]Psychiatry, University Hospitals Case Medical Center, Cleveland, USA ; [2]Psychiatry, Massachusetts General Hospital, Boston, USA ; [3]Biostatistics, Forest Research Institute, Jersey City, USA ; [4]Medical Division, Gedeon Richter Plc, Budapest, Hungary ; [5]Clinical Development, Forest Research Institute, Jersey City, USA

Introduction: Cariprazine is a potent dopamine D_3 and D_2 receptor partial agonist with preferential binding to D_3 receptors.

Objective: Summarize data from two Phase III, randomized, double-blind, placebo-controlled, flexible-dose, 3-week trials of cariprazine 3-12mg/d (NCT01058096) and cariprazine 3-6mg/d or 6-12mg/d (NCT01058668) in adults with bipolar I disorder and acute manic or mixed episodes.

Aims: Evaluate the efficacy, safety, and tolerability of cariprazine in mania associated with bipolar I disorder.

Methods: Primary and secondary efficacy parameters were change from baseline to Week 3 on the Young Mania Rating Scale (YMRS) and Clinical Global Impressions-Severity (CGI-S), respectively, and were analyzed using a mixed-effects model for repeated measures.

Results: Randomized patient populations: 312 (NCT01058096; 154 placebo, 158 cariprazine 3-12mg/d) and 497 (NCT01058668; 161 placebo, 167 cariprazine 3-6mg/d, 169 cariprazine 6-12mg/d). Improvement from baseline to Week 3 on YMRS was significantly greater for each cariprazine group vs placebo (P<0.001): least square mean difference (LSMD) was -4.3 (3-12mg/d), -6.1 (3-6mg/d) and -5.9 (6-12mg/d). For each cariprazine group, significantly more patients met YMRS response and remission criteria vs placebo. Cariprazine also was significantly superior to placebo on the CGI-S: LSMD was -0.4 (3-12mg/d, P=.0027), -0.6 (3-6mg/d, P<.001), -0.6 (6-12mg/d, P<.001). The only common cariprazine-related TEAEs (≥5% and twice rate of placebo) that occurred in both studies were akathisia and tremor. Changes in metabolic parameters were small and similar to placebo in both studies.

Conclusions: Cariprazine was effective and generally well tolerated in the treatment of bipolar mania.

https://doi.org/10.1016/S0924-9338(14)78200-8 Published online by Cambridge University Press