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# EFFICACY AND SAFETY OF CARIPRAZINE IN PATIENTS WITH ACUTE EXACERBATION OF SCHIZOPHRENIA: RESULTS OF TWO PHASE III TRIALS

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**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 2 Phase III, randomized, double-blind (6-week), placebo-controlled trials of fixed-dose cariprazine (3mg/d and 6mg/d, NCT01104766) and flexible-dose cariprazine (3-6mg/d and 6-9mg/d, NCT01104779) in adults with acute exacerbation of schizophrenia.

**Aims:** Evaluate the efficacy, safety, and tolerability of cariprazine in schizophrenia.

**Methods:** Primary and secondary efficacy parameters were change from baseline to Week 6 in Positive and Negative Syndrome Scale (PANSS) and Clinical Global Impressions-Severity (CGI-S), respectively, and were analyzed using a mixed-effects model for repeated measures.

**Results:** Randomized patient populations: 617 (NCT01104766; 153 placebo, 155 cariprazine 3mg/d, 157 cariprazine 6mg/d, 152 aripiprazole) and 446 (NCT01104779; 147 placebo, 151 cariprazine 3-6mg/d, 148 cariprazine 6-9mg/d). Improvement from baseline to Week 6 on PANSS total scores was significantly greater with cariprazine vs placebo: least square mean difference (LSMD) was -6.0 (3mg/d, *P*=.0044), -6.8 (3-6mg/d, *P*=.0029), -8.8 (6mg/d, *P*<.0001), and -9.9 (6-9mg/d, *P*<.0001). Cariprazine was significantly superior to placebo on CGI-S: LSMD was -0.4 (3mg/d, *P*=.0044), -0.3 (3-6mg/d, *P*=.0115), -0.5 (6mg/d, *P*<.0001), and -0.5 (6-9mg/d, *P*=.0002). Aripiprazole (active control, NCT01104766) was superior to placebo on both measures (LSMD: PANSS=-7.0, *P*=.0008; CGI-S=-0.4, *P*=.0001). The only common cariprazine-related TEAE (≥5% and twice rate of placebo) that occurred in both studies was akathisia. Changes in metabolic parameters were small and similar to placebo in both studies.

**Conclusion:** Cariprazine was effective and generally well tolerated in the treatment of schizophrenia.

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