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Presented at the 16th BMJ World Congress on Menopause: Menopause 2013, Vancouver, Canada

REFERENCES


CONCLUSIONS

In this pooled analysis of 2 open-label long-term studies of adult patients with schizophrenia, treatment with cariprazine up to 48 weeks was generally safe and well tolerated.

No antipsychotics emerged with continued long-term treatment that was comparable to cariprazine.

Similar to some antipsychotics, cariprazine was associated with EPS-related TEAEs, although incidences were generally mild to moderate in intensity and typically did not result in discontinuation.

Patients who received long-term treatment with cariprazine had minimal change in weight over time, including metabolic, liver function, and cardiovascular parameters.

Cariprazine treatment was not associated with protection against excess mortality or postgustation.

Suicidal Ideation and Behavior

TEAEs of suicidal ideation occurred in 7 (1%) patients; including 1 completed suicide during the open-label treatment period (considered unrelated to treatment).

Suicide ideation was recorded in 40 (6%) patients (1.8%); no SAEs were associated with suicidality.

Postmarketing and Safety

No SAEs associated with EPS were reported; discontinuations due to EPS-related TEAEs were uncommon (1.6%).

Gastrointestinal Symptoms

Nausea was reported in 12% of patients, and most frequently occurred early in treatment (10% of patients).

Diarrhea was reported in 3% of patients. Diarrhea was most frequently reported early in treatment (2.3% of patients).

Dyspepsia was reported in 5% of patients. Dyspepsia was most frequently reported early in treatment (2.3% of patients).

Hypertension was reported in 10% of patients. Hypertension was most frequently reported early in treatment (2.3% of patients).

Gastritis was reported in 1% of patients. Gastritis was most frequently reported early in treatment (0% of patients).

Abdominal pain was reported in 2% of patients. Abdominal pain was most frequently reported early in treatment (0.7% of patients).

Dyspepsia was reported in 5% of patients. Dyspepsia was most frequently reported early in treatment (2.3% of patients).

Insomnia was reported in 13% of patients. Insomnia was most frequently reported early in treatment (1.3% of patients).

Headache was reported in 12% of patients. Headache was most frequently reported early in treatment (2.3% of patients).

Restlessness was reported in 7% of patients. Restlessness was most frequently reported early in treatment (0% of patients).

Fever was reported in 2% of patients. Fever was most frequently reported early in treatment (0% of patients).

Dizziness was reported in 4% of patients. Dizziness was most frequently reported early in treatment (0% of patients).

Asthenia was reported in 7% of patients. Asthenia was most frequently reported early in treatment (2.3% of patients).

Cough was reported in 3% of patients. Cough was most frequently reported early in treatment (0% of patients).

No other serious treatment-emergent adverse reactions occurred with an incidence of ≥1% in any treatment group.

The mean increase in fasting glucose (4.5 mg/dL) was similar to that observed during the 6-week lead-in studies. Safety and Tolerability of Cariprazine in Long-Term Treatment of Schizophrenia: Integrated Summary of Safety Data

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Support for these Cincinnati, Inc, Garden Ridge, TX
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