RELAPSE PREVENTION WITH CARIPRAZINE IN PATIENTS WITH EARLY-STAGE SCHIZOPHRENIA

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OBJECTIVE

The objective of the poster is to present the efficacy of cariprazine in preventing relapse in patients with early-stage schizophrenia.

KEY TAKE-AWAYS

In patients within the first 5 years of schizophrenia, the relative risk of relapse was **81% reduced** with cariprazine.

This means the prevention of **one additional relapse after each third patient** exposed to cariprazine vs placebo.

Cariprazine seems to be a **good treatment option** for early-stage patients for preventing relapse.

Presented at the 32nd European Congress of Psychiatry, 6-9 April 2024, Budapest

EPP0461

INTRODUCTION

- Relapse is defined as the **return of psychotic symptoms after a period of improvement/stability**.
- Relapse is often associated with the disruptive re-hospitalization of patients. Importantly, relapse history is a strong predictor of subsequent relapses and **poorer outcomes**. Therefore, relapse prevention in the beginning of the disorder is especially important.
- **Cariprazine**, a novel D3-D2 partial agonist, has been effective in preventing relapse compared to placebo in stabilized patients with schizophrenia.

METHODS

- Post-hoc analysis of data from a **~96 weeks, multicentre, randomized, double-blind, placebo-controlled, parallel-group study** in adults with schizophrenia. The study was composed of two parts: a 20-week open-label treatment phase and a double-blind treatment phase up to 72 weeks. During the open-label phase, patients were stabilized with cariprazine 3.0-9.0 mg/day. Then, they were randomized to continue cariprazine (fixed dosing: 3.0, 6.0, or 9.0 mg/day) or receive placebo.
- Relapse was defined as a **deterioration of symptom scores** as measured by the Positive Negative Syndrome Scale (PANSS), **admission** to a psychiatric **hospital**, exhibiting **aggressive behaviour**, or **risk of suicide**.
- In the present analysis, patients with a schizophrenia diagnosis history of **0-5 years** were defined as early-stage patients. Baseline characteristics, and risk ratios (after the double-blind phase) with number-needed-to-treat (NNT) were calculated. The difference between cariprazine and placebo was also analyzed with time to relapse as the outcome, using Kaplan-Meier survival analysis.

RESULTS

- Out of 200 patients, 71 (35.5%) met the early-stage criteria: 32 patients in the cariprazine (CAR) and 39 in the placebo (PBO) arm.
- The average number of previous hospitalisations was comparable in the two groups (CAR: 2.3; PBO: 2.6), as was the severity of illness: mean PANSS Total score: 89.2 (CAR), 90.4 (PBO). Patients in both groups were **highly compliant** (pill-count: CAR: 98.2%; PBO: 99.5%). The main reported adverse effects were headache (CAR: 11.3%, PBO: 7.0%), insomnia (CAR: 5.6%, PBO: 4.2%), and increased triglycerides (CAR: 5.6%, PBO: 1.4%), discontinuation due to adverse event was 3.1% in the CAR and 2.6% in the PBO group.
- Altogether, **9.4% of patients relapsed in the cariprazine group** compared to **48.7% on placebo** (risk ratio=0.19 (95% confidence interval (CI): 6.3-59.2%, p=0.0041;NNT: 2.5 (95%CI: 1.7-5.1).

Figure 1. Study design

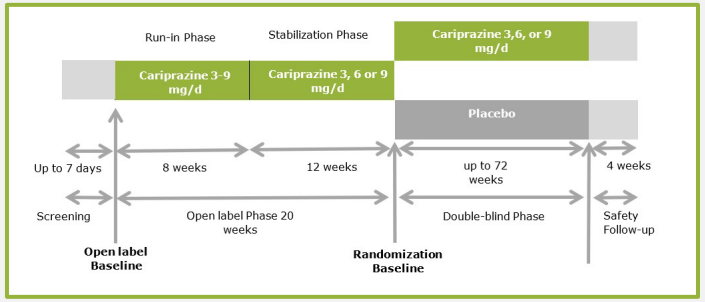

Table 1. Baseline & treatment characteristics

	Early-stage Schizophrenia (n = 71)	
	CAR (n = 32)	PBO (n = 39)
Demographics		
Age, mean (SD)	31.6 (7.7)	31.6 (8.1)
Sex, n (%)		
Men	15 (46.9)	30 (76.9)
Women	17 (53.1)	9 (23.1)
Illness characteristics		
Age at diagnosis, mean (SD)	29.1 (7.7)	28.8 (7.9)
Duration of illness, mean (SD), years	2.51 (1.0)	2.75 (1.2)
No. of previous hospitalisations, mean (SD)	2.25 (3.05)	2.64 (3.29)
CGI-S score, mean (SD)	4.66 (0.6)	4.67 (0.5)
PANSS Total score, mean (SD)	89.19 (8.9)	90.36 (8.3)
Treatment		
Compliance %	98.2	99.5
Dosing		
3.0 mg/day	7 (21.9)	
6.0 mg/day	12 (37.5)	
9.0 mg/day	13 (40.6)	

Figure 2. Kaplan-Meier plot of survival probability of relapse