

# CARIPRAZINE IN FEMALE SCHIZOPHRENIA PATIENTS

## Real-world evidence from an observational study

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**Cariprazine was found to be effective in women with schizophrenia in a real-life setting.**



**70% of doctors were very satisfied or satisfied with cariprazine's effectiveness.**

### OBJECTIVE

To evaluate the effectiveness of cariprazine in women in a real-world setting.

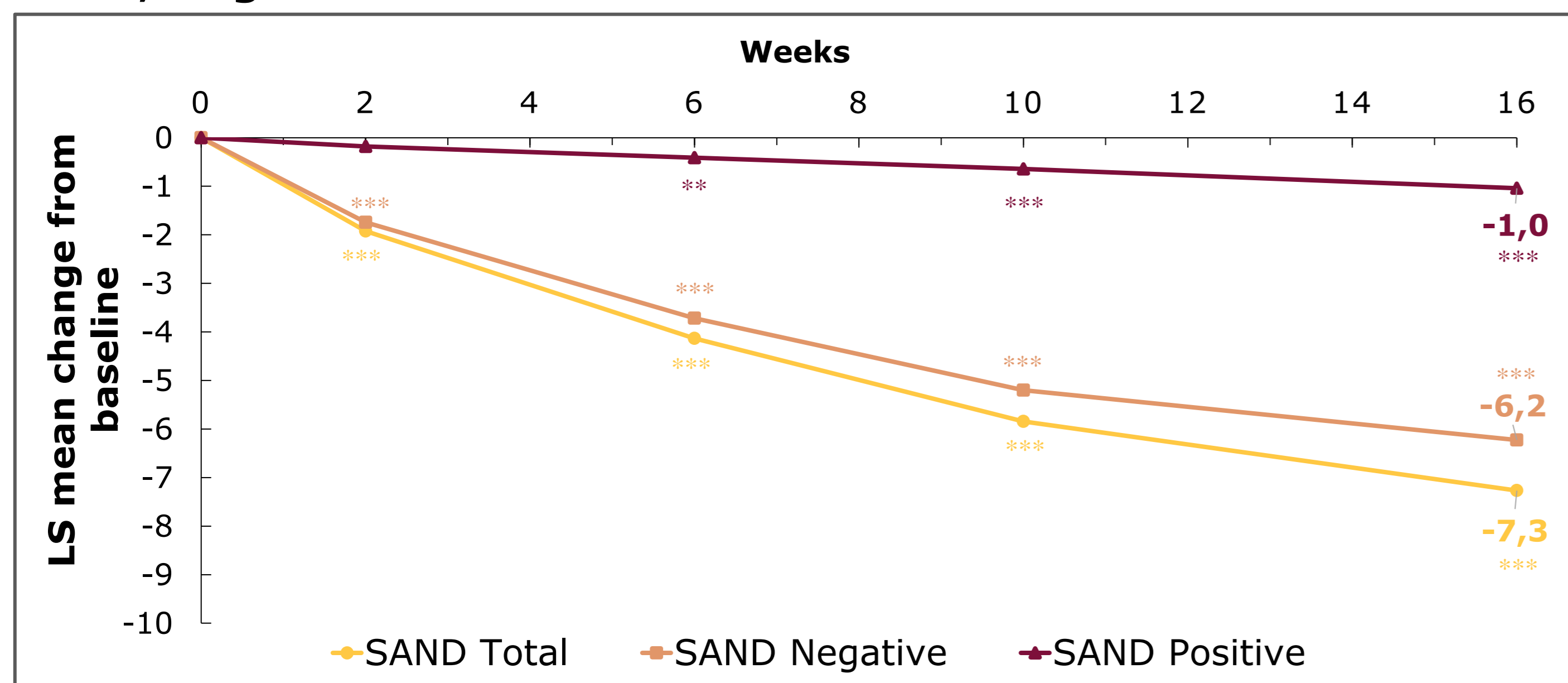
### METHODS

- This was an open-label, flexible-dose, 16-week (5 visit), observational study of cariprazine involving 116 outpatients in Latvia.
- The primary outcome measure was an array of anamnesis-based clinical questions on schizophrenia symptoms (positive symptoms: hallucinations, delusions; negative symptoms: anhedonia, blunted effect, avolition/apathy, alogia, asociality) rated on a 7-point scale (Short Assessment of Negative Domains (SAND)).
- Other outcome measurements were the Clinical Global Impression Improvement (CGI-I) and Severity (CGI-S) scales.
- A mixed model for repeated measures was fit to the data to evaluate the mean change from baseline for all visits. In this post-hoc analysis, only women were analyzed.

### RESULTS

- Out of the 116 patients, 47 were women.
- There was a significant change from baseline to week 16 in the SAND total (-7.3,  $p < 0.001$ ), negative (-6.2,  $p < 0.001$ ) and positive scores (-1.0,  $p < 0.001$ ).

**Figure 1. Least Square Mean Change from Baseline in SAND Total, Negative and Positive scores**



**Table 2. CGI-S & CGI-I in women**

	BASELINE	FINAL VISIT
<b>CGI – Severity</b>		
Score, mean (SD)	4.55 (0.12)	3.85 (0.14)
Mean change from baseline (MMRM)	-	-0.82 (0.11) ***
Score, n (%)		
Normal	-	-
Borderline mentally ill	-	1 (2.1)
Mildly ill	5 (10.6)	18 (38.3)
Moderately ill	17 (36.2)	18 (38.3)
Markedly ill	19 (40.4)	7 (14.9)
Severely ill	6 (12.8)	3 (6.4)
Among the most extremely ill patients	-	-
<b>CGI – Improvement</b>		
Score, mean (SD)	-	2.94 (0.15)
Score, n (%)		
Very much improved	-	1 (2.1)
Much improved	-	17 (36.2)
Minimally improved	-	18 (38.3)
No change	-	7 (14.9)
Minimally worse	-	3 (6.4)
Much worse	-	1 (2.1)
Very much worse	-	-

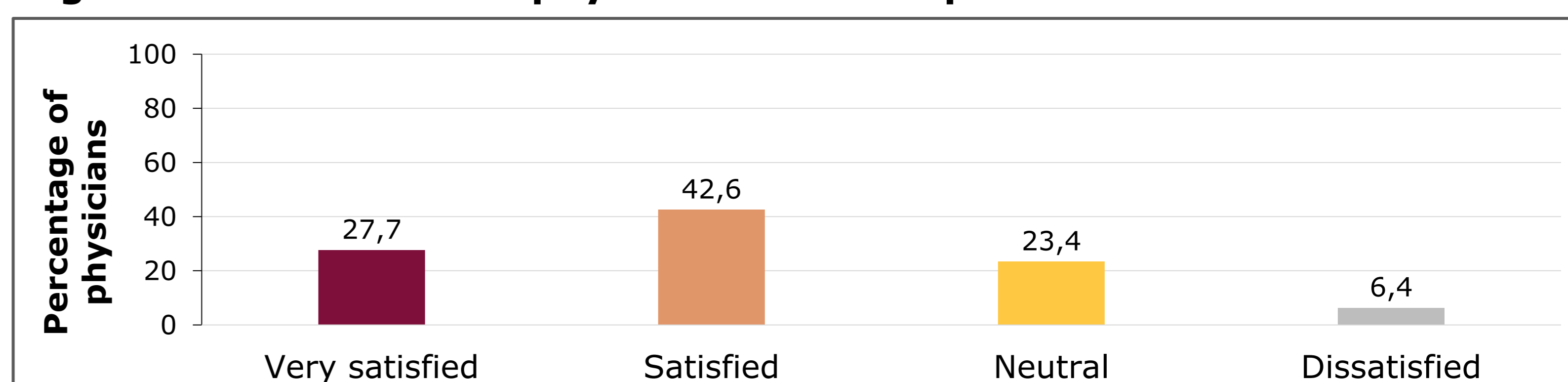
\*\*\* $p < 0.001$

**Table 1. Baseline characteristics**

<b>Population</b>	
Safety population, women, n (%)	47 (100)
<b>Demographics</b>	
Age, mean (SD), y	40.5 (12.2)
Weight, mean (SD), kg	78.0 (20.7)
BMI, mean (SD), kg/m <sup>2</sup>	27.7 (7.0)
<b>Schizophrenia characteristics</b>	
Duration of illness, mean (SD), y	9.7 (7.6)
Schizophrenia diagnosis, n (%)	
Paranoid schizophrenia	34 (72.3)
Other schizophrenia	8 (17.0)
Undifferentiated schizophrenia	3 (6.4)
<b>Inclusion reasons, n (%)</b>	
Insufficient effectiveness	38 (80.9)
Positive symptoms	14 (29.8)
Negative symptoms	39 (83.0)
Affective symptoms	23 (48.9)
Cognitive symptoms	21 (44.7)
Severe adverse effects	22 (46.8)
Patient desire	31 (66.0)
<b>Previous therapy, n (%) *</b>	
Aripiprazole	11 (23.4)
Risperidone	6 (12.8)
Haloperidol	6 (12.8)
Olanzapine	6 (12.8)
Quetiapine	5 (12.6)
<b>Cariprazine starting dose, n (%)</b>	
1.5 mg/day	43 (91.5)
3.0 mg/day	2 (4.3)
4.5 mg/day	1 (2.1)
6-0 mg/day	1 (2.1)
<b>Patient disposition</b>	
Completed study, n (%)	39 (83.0)
Premature discontinuation, n (%)	8 (17.0)
<b>SAND scores</b>	
Total, mean (SD)	18.3 (0.8)
Positive score, mean (SD)	1.8 (0.3)
Negative score, mean (SD)	16.5 (0.8)

\*Type of antipsychotic taken by >10% of patients within the last month before study entry

**Figure 3. Satisfaction of physicians with cariprazine's effectiveness**



Disclosure: Zs. B. Dombi and Gy. Németh are employees of Gedeon Richter Plc.