

been accepted as a valuable outcome measure in many psychiatric conditions; thus, identification of contributing factors may help to improve overall outcome. Moreover, close monitoring of adverse effects of illness on QoL in healthy siblings may become a part of larger prevention strategies.

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#### Reference

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#### EW0481

### Diagnosis of predominant negative symptoms: Post-hoc analyses of a phase 3 clinical trial with cariprazine monotherapy and risperidone

I. Laszlovszky\*, Á. Barabácssy, E. Szalai, B. Szatmári, J. Harsányi, G. Németh

Gedeon Richter Plc, Medical Division, Budapest, Hungary

\* Corresponding author.

*Objective* To present, post hoc analyses from a controlled, prospective study of predominant negative symptoms (PNS) of schizophrenia on baseline patient characteristics, severity of symptoms and their variability among participating countries.

*Methods* Data were analyzed from a phase 3, randomized, double-blind, active-controlled, parallel-group study in adult PNS patients with schizophrenia (EudraCT Number 2012-005485-36). Subjects with a PANSS factor score for negative symptoms (PANSS-FSNS)  $\geq 24$  and no pseudo-specific factors (e.g. high positive symptoms, extrapyramidal symptoms, depression) were randomized to cariprazine 4.5 mg/d (dose range: 3–6 mg/d) or risperidone 4 mg/d (dose range: 3–6 mg/d) for 26 weeks. Baseline values of PANSS-FSNS, individual PANSS items, personal and social performance (PSP), and clinical global impression of severity (CGI-S) were analyzed based on the data gained from 11 European participating countries.

*Results* Average PANSS-FSNS of patients was  $27.6 \pm 2.48$ , reflecting severe negative symptoms. Patients were moderately ill (CGI-S  $4.2 \pm 0.75$ ), with marked difficulties (PSP  $48.4 \pm 10.78$ ) predominantly in social functioning. The investigated patient population was fairly homogeneous as shown by small variability in all three scores. Moreover, baseline values in the 11 countries presented low variability while number of enrolled patients per country showed high variance ( $n = 7–118$ ). Narrative description of symptoms and individual PANSS items rated as most severe and prominent were in high correlation.

*Conclusion* Post hoc evaluation of this predominant negative symptom study showed that, this patient population can be identified reliably by psychiatrist. Additional training on the judgment of personal and social relationships can increase the diagnostic accuracy.

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#### EW0482

### Day-to-day and social functioning of patients with negative symptoms of schizophrenia: Post-hoc analyses of a phase 3 clinical trial with cariprazine monotherapy and risperidone

Á. Barabácssy\*, I. Laszlovszky, B. Szatmári, E. Szalai, J. Harsányi, G. Németh

Gedeon Richter Plc, Medical Division, Budapest, Hungary

\* Corresponding author.

*Introduction* Negative symptoms have substantial impact on day-to-day functioning of patients with schizophrenia affecting their ability to perform activities of daily living and to maintain personal relationships.

*Objective* To present post hoc data on day-to-day and social functioning of patients with predominant negative symptom (PNS) of schizophrenia, treated with cariprazine versus risperidone.

*Methods* Data from 26 weeks, phase 3, randomized, double-blind, active-controlled study in PNS patients were analyzed (EudraCT 2012-005485-36). Subjects with PNS (PANSS factor score for negative symptoms  $\geq 24$ ) were randomized to cariprazine 4.5 mg/d or risperidone 4 mg/d. Change from baseline to end of treatment on the personal and social performance scale (PSP) and PANSS prosocial subscale (P3, P6, N2, N4, N7, G16) was analyzed.

*Results* Significantly greater improvements were seen with cariprazine compared to risperidone in the change from baseline to end of treatment on the PSP (LSMD + 4.632 [2.71, 6.56];  $P < 0.001$ ) from week 10 onwards (effect size 0.48); in the PSP subdomains of self-care (LSMD  $-0.2$  [ $-0.3$ ;  $-0.1$ ];  $P = 0.004$ ), personal and social relationships (LSMD  $-0.2$  [ $-0.4$ ;  $-0.1$ ];  $P < 0.001$ ) and socially useful activities (LSMD  $-0.4$  [ $-0.5$ ;  $-0.2$ ];  $P < 0.001$ ); in the number of patients who improved at least 10 points on the PSP (OR 2.1;  $P = 0.001$ ) or shifted to a higher category (OR 2.2;  $P = 0.001$ ); and on the PANSS prosocial subscale (LSMD  $-0.8$  [ $-1.41$ ,  $-0.16$ ];  $P = 0.014$ ).

*Conclusion* Post hoc evaluation of this study showed that cariprazine treatment is associated with a clinically relevant improvement in patient functioning and social competence compared to risperidone.

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#### EW0483

### The relationship between negative symptoms and cognitive functioning in patients with an at risk mental state for psychosis

L. Leanza\*, L. Egloff, E. Studerus, C. Andreou, U. Heitz, K. Beck, S. Menghini-Müller, S. Ittig, A. Riecher-Rössler

University of Basel Psychiatric Hospital, Center for Gender Research and Early Detection, Basel, Switzerland

\* Corresponding author.

*Introduction* Negative symptoms and cognitive impairments are both present in patients with an at risk mental state (ARMS) for psychosis and negatively affect functioning and outcome. According to previous studies in patients with first-episode psychosis, negative symptoms are negatively associated with cognitive functioning while positive symptoms do not seem to be associated. Yet, little is known about the specific relationship of negative symptoms and cognitive functioning in ARMS patients.

*Objective* To evaluate, the relationship between negative symptoms and cognitive functioning in ARMS patients.

*Methods* Data of 154 ARMS patients were collected within the prospective Basel early detection of psychosis (FePsy) study. Negative symptoms were assessed with the SANS, positive psychotic symptoms with the BPRS, cognitive functioning with an extensive neuropsychological test battery. Multiple regressions were applied and results were controlled for age and gender.

*Results* Regression analyses showed a significant, negative association between negative but not positive psychotic symptoms and cognitive functioning, showing the strongest association with verbal fluency (see Fig. 1). However, results mainly did not withstand correction for multiple testing.