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New data show XEPLION® significantly delays time to relapse compared to treatment as usual with oral antipsychotic monotherapy

PROSIPAL study also shows XEPLION® lowers relapse rates in people with schizophrenia compared to oral treatments

BEERSE, Belgium, 4 March 2014: Janssen Pharmaceutica NV has announced results of the Prevention of Relapse With Oral Antipsychotics Versus Injectable Paliperidone Palmitate (PROSIPAL) study* at the 22nd European Congress of Psychiatry in Munich, Germany, 1-4 March 2014. Data showed that XEPLION® (paliperidone palmitate), a once-monthly, long-acting therapy, significantly lengthened the time to relapse during the two year treatment phase, as well as significantly lowering relapse rates in people with schizophrenia, compared to treatment as usual with the investigator's choice of oral antipsychotic treatment.¹

PROSIPAL was a 24-month, prospective, randomised, open-label, rater-blinded study, investigating the efficacy of XEPLION®, compared with oral antipsychotic monotherapy treatment in 715 patients with recently-diagnosed schizophrenia (1–5 years since diagnosis). The average duration of illness from diagnosis to the beginning of the study was 2.9±1.5 years. By the end of the 24-month treatment phase, time to relapse was significantly longer with XEPLION® compared to oral antipsychotics (mean±SE: 616±10.9 days vs 603±13.1 days, p=0.0191).¹ In addition, relapse rates were significantly lower in the XEPLION® group (n=352) vs the oral antipsychotics group (n=363); 14.8% vs 20.9%; p=0.0323 respectively, reflecting a relative risk reduction of 29.4%.¹

“Each relapse of schizophrenia that patients suffer can negatively affect their long-term functioning and quality of life; early intervention and relapse prevention are therefore key aims for healthcare practitioners,” said Professor Philip Gorwood, Hopital Sainte-Anne, Paris, France and investigator in the PROSIPAL study. “This study shows that XEPLION® may protect patients earlier and for longer than oral antipsychotic treatments and is therefore a valuable option for the long-term treatment of patients with recently diagnosed schizophrenia.”

The PROSIPAL data also showed that significant improvements in positive and negative syndrome scale (PANSS) total scores from baseline to each subsequent visit were observed within both treatment groups (p<0.0001).¹ The reduction of psychotic symptoms in PANSS scores was significantly superior with XEPLION® compared to oral antipsychotic monotherapy at treatment day 8 (p=0.0213) and showed a trend in favour of XEPLION® at endpoint (p=0.0745).¹ The most frequently (≥5%) mentioned treatment emergent adverse events (TEAEs) for XEPLION® or the oral antipsychotic group were, respectively: weight increase (15.9%, 17.4%), headache (11.1%, 8.5%), insomnia (9.7%, 8.0%), schizophrenia (8.2%, 9.6%), nasopharyngitis (7.1%, 5.0%), injection site pain (6.8%, 0.0%), anxiety (5.7%, 4.4%), tremor (5.1%, 2.2%) and suicidal ideation (4.5%, 5.5%). The study results showed no new safety signals in the XEPLION® group.¹

Long-acting therapies can help people with schizophrenia to maintain continuous treatment, and avoid further relapses,² allowing them to return to everyday activities such as work, education and independent living, which can support their recovery.

Clinical guidelines recommend that the optimal treatment package for people with schizophrenia is a combination of medication along with psychotherapy, psycho-education and self-help.³ Evidence

suggests that early introduction of therapies incorporating social and psychological interventions, as well as medication, may be an important factor in realising a person's long-term goals.^{3,4}

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Notes to editor

About the PROSIPAL study¹

The PROSIPAL study is a 24-month, prospective, randomized, active-controlled, open-label, rater blinded, multicenter, international study conducted to compare XEPLION[®] versus treatment with oral antipsychotic monotherapy.

Primary objective: To assess the efficacy (primarily through time to relapse) of XEPLION[®] compared with treatment as usual with oral antipsychotic monotherapy:

- Either aripiprazole, quetiapine, olanzapine, paliperidone extended release, risperidone or haloperidol
- Until relapse** or over maximally 24 months (whichever comes first), in the treatment of recently diagnosed (1–5 years since diagnosis) schizophrenia

Primary efficacy endpoint

- Time to relapse

Secondary efficacy endpoints

- Relapse rates
- Changes from baseline in PANSS total score
- Mean score and changes from baseline in global severity of illness (CGI-S, CGI-C)
- Changes from baseline in level of functioning (PSP)

Additional secondary outcome measures

- Percentage of treatment responders ($\geq 30\%$ increase in PANSS total score at endpoint versus BL)
- Changes from BL in PANSS sub-domains/symptom factors
- Hospitalisation
 - Rate (psychiatric reasons) during study
 - Total number and mean duration of psychiatric hospitalisations
- Safety and tolerability of XEPLION[®] compared with oral antipsychotics, until relapse, or over maximally 24 months (whichever comes first)

- Measures of patient's mental health and well-being:
 - SF-36 (Social Functioning, Role Emotional and Mental Health subscales), European Quality of Life – 5 Dimensions (EQ-5D), Subjective Well-Being under Neuroleptics Scale (SWN)
- Patient treatment satisfaction:
 - Treatment Satisfaction Questionnaire for Medication (TSQM), Physician treatment satisfaction (7-point categorical scale)
- Exploratory:
 - Health Resource Use Questionnaire (HRUQ)
 - Alcohol and substance use (Clinician Rating Alcohol Use Scale [CRAUS], Clinician Rating Substance Use Scale [CRSUS])
 - Patient's suicidality (Intersept Scale for Suicidal Thinking-modified [ISST-M])

Safety endpoints

- Adverse events (AEs)
- Weight gain: $\geq 7\%$ weight increase
- Body Mass Index (BMI) increase

**Based on Csernansky criteria

About XEPLION® (paliperidone palmitate)

XEPLION® is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, XEPLION® may be used without prior stabilization with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed. For complete EU prescribing information, please visit: www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002105/WC500103317.pdf

About Schizophrenia

Schizophrenia affects people from all countries, socio-economic groups and cultures. Its prevalence is similar around the world – almost one person in every 100 will develop schizophrenia before they reach the age of 60, with men and women equally at risk.⁵

There is no single cause of schizophrenia. Different factors acting together are thought to contribute to the development of the illness. Both genetic and environmental factors seem to be important.⁶ The symptoms of schizophrenia can include hallucinations, delusions, lack of emotional response, social withdrawal/depression, apathy and a lack of drive or initiative.

While schizophrenia is a lifelong condition, there are treatments available that allow people with schizophrenia to get better. Clinical guidelines recommend that the optimal treatment package for people with schizophrenia is a combination of medication along with psychotherapy, psycho-education and self-help.³ Beyond simply controlling symptoms, effective treatment can enable people with schizophrenia to enjoy a more fulfilling life, which may include returning to work or study, independent living and social relationships, which in turn can aid their recovery.

For more information about schizophrenia, as well as helpful resources and interactive tools for those affected by the condition, visit www.schizophrenia24x7.com. This site is sponsored by Janssen Pharmaceutica NV.

About Janssen Pharmaceutica NV

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen Pharmaceutica NV and its affiliates worldwide are at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and health care professionals have access to the latest treatment information, support services and quality care. Please visit www.janssen.com for more information.

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