



INVEGA® Approved as First and Only Antipsychotic Treatment for Schizoaffective Disorder in the European Union

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The European Commission has approved the first antipsychotic treatment for schizoaffective disorder. INVEGA® (paliperidone ER) is now indicated for the treatment of psychotic or manic symptoms of schizoaffective disorder. Effect on depressive symptoms has not been demonstrated.

The decision follows a positive recommendation by the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency. The CHMP concluded that the new therapeutic indication for INVEGA® brings significant clinical benefit in comparison with existing therapies.

Schizoaffective disorder is a chronic and disabling mental illness, characterised by both symptoms of schizophrenia and a major mood disorder, such as bipolar disorder or depression. Patients may experience the clinical symptoms of schizophrenia, such as hallucinations or delusions, as well as symptoms of mania and/or depression. Schizoaffective disorder is thought to be one-third as common as schizophrenia, with an estimated prevalence of approximately 1 in every 300 people¹. Schizoaffective disorder may also account for up to one-quarter of admissions to inpatient mental health facilities².

"Janssen is committed to helping improve the lives of people with serious mental illness and has a long history of developing innovative medicines in this field," said Dr Christophe Tessier*, Medical Affairs Director, Psychiatry, Janssen. "We are proud to be able to bring to market the first antipsychotic treatment for schizoaffective disorder in Europe - a difficult to diagnose condition associated with a high rate of hospitalisations and suicidal behaviour."

The approval is based on two international, randomised, double-blind, placebo-controlled 6-week studies in patients diagnosed with schizoaffective disorder^{3,4}. In the first six-week study, patients (n=316) received one of two daily doses of INVEGA®: 6 mg with the option to reduce to 3 mg, or 12 mg with the option to reduce to 9 mg, or placebo³. In the second study, patients (n=311) were randomised to flexible doses of INVEGA® (3-12 mg once daily) either as monotherapy or in addition to treatment with mood stabilisers and/or antidepressants or placebo⁴.

Efficacy was evaluated by the change in patients' symptoms after six weeks as measured by the positive and negative syndrome scale (PANSS). The results for INVEGA® in both studies were superior to placebo. In the first study, patients receiving the higher dose of INVEGA® had a significant decrease in their symptom score compared with those receiving placebo (-32.4 compared with -24.1, p=0.003)³. The lower dose of INVEGA® was not significantly different from placebo (p=0.187). In the second study, the mean decrease in symptom score was -20.0 in the INVEGA® group and -10.8 in the placebo group³ (p=0.0001)⁴. Furthermore, among patients with prominent manic symptoms as measured by the Young Mania Rating Scale (YMRS baseline score \geq 16) INVEGA® resulted in significant improvements in manic symptomatology compared to placebo.

"These two studies combined represent the largest set of prospective data in patients with schizoaffective disorder and provide important insights into this understudied disease", said Dr Carla M. Canuso**, Johnson & Johnson Pharmaceutical Research and Development, LLC, Titusville, NJ and lead investigator of the two studies. "INVEGA® was proven to be effective both as a monotherapy and as an adjunctive therapy in reducing psychotic and manic symptoms and provides a welcome treatment option for this debilitating condition."

About schizoaffective disorder

Schizoaffective disorder usually develops in early adulthood and is more common in women. It can affect all aspects of a person's daily life, including work, personal relationships and the ability to take care of oneself. Patients with schizoaffective disorder have a high rate of hospitalisations and a higher rate of co-morbid substance abuse than patients with schizophrenia^{5,6}. In addition, patients with schizoaffective disorder appear to be at greater risk of suicidal behaviour than patients with schizophrenia and mood disorders^{5,6}.

About INVEGA® (paliperidone ER)

INVEGA® (paliperidone ER), an atypical antipsychotic medication, was first approved in Europe in June 2007 for the treatment of schizophrenia. INVEGA® is a novel molecule (paliperidone) delivered via an osmotic drug delivery system (OROS®) which provides a steady, smooth release of medication over 24 hours. This reduces the peaks and troughs in drug plasma levels associated with immediate release oral formulations and leads to a low potential for increased side effects as well as ensuring

consistent efficacy. INVEGA® is the first antipsychotic medication to have significantly improved personal and social performance recognised in its Summary of Product Characteristics (SPC). Further information about INVEGA® can be found at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000746/human_med_000848.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d124&jsenabled=true

About Janssen

Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS, Hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g. diabetes). Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency. More information can be found at <http://www.janssen-emea.com/>.

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