INVEGA® SUSTENNA® Found to Delay Time to Relapse in Individuals With Schizoaffective Disorder, Schizophrenia

Janssen Pharmaceuticals, Inc. has announced the results of the company’s schizoaffective relapse prevention study of once-monthly, atypical, long-acting antipsychotic paliperidone palmitate (INVEGA® SUSTENNA®). The trial found that INVEGA SUSTENNA, currently indicated for the treatment of schizophrenia, met its primary end-point of delayed time to and reduced risk of relapse compared with placebo as monotherapy and adjunctive therapy in patients with schizoaffective disorder. The medication also showed significant efficacy in manic and depressive mood symptoms and psychosis, as well as improved and maintained patient functioning. Results of the study were presented at the 167th Annual Meeting of the American Psychiatric Association (APA).

The 15-month, randomized, double-blind, placebo (PBO)-controlled, international study evaluated 334 adults (INVEGA SUSTENNA, n = 164; PBO, n = 170) who met the Diagnostic and Statistical Manual of Mental Disorders, fourth edition, diagnosis of schizoaffective disorder experiencing an acute exacerbation of psychotic symptoms with prominent mood symptoms as determined by the Young Mania Rating Scale and/or the Hamilton Depression Rating Scale.

Prior to randomization, individuals were first stabilized with INVEGA SUSTENNA (78 to 234 milligrams) either as monotherapy or an adjunct to antidepressants or mood stabilizers during a 13-week, open-label, flexible-dose, lead-in period; they then continued into a 12-week open-label, fixed-dose stabilization period. Afterward, stable patients were randomized to treatment with INVEGA SUSTENNA once every 4 weeks or the placebo, and they were evaluated until relapse, discontinuation, or completion of the 15-month relapse prevention period.

For the study, relapse was defined as psychiatric hospitalization or any intervention to prevent hospitalization due to the worsening of symptoms; clinically significant self-injury, suicidal or homicidal ideation, or violent behaviors; or a worsening of schizoaffective symptoms.

Researchers found that INVEGA SUSTENNA significantly delayed time to relapse compared with placebo ($p < 0.001$). A higher percentage of patients relapsed in the placebo group (33.5%) than in the INVEGA SUSTENNA group (15.2%), with the risk of relapse being approximately three times higher in the placebo group.

A decrease in the risk of relapse occurred regardless of whether INVEGA SUSTENNA was taken alone or with another medication in a subgroup analysis. The risk of relapse was approximately three times higher in the placebo group when INVEGA SUSTENNA was taken alone or with another medication in a subgroup analysis.

Audio Programs Improve Children’s Outlook While They Sleep

Sleep’N Sync (www.sleepnsync.com) is a noninvasive, patent-pending product that helps children become more receptive and acquire the skills necessary to live optimistic and successful lives.

Sleep’N Sync provides various audio-tape programs focusing on numerous themes kids face in life today, such as bullying, dealing with anger, flexibility, test taking, reading and comprehension, and communication skills.

All programs are thoroughly researched and provide children with the skills and strategies necessary to succeed. In addition, the audiotapes are engineered with a background soundtrack with binaural beats, which synchronize children’s brainwaves and create greater receptiveness while children sleep.

Each program includes an audiotrack designed to be played for children on a daily basis for 6 weeks, caregiver instructions, evaluation forms to track and measure progress, and a bonus binaural beats musical track.

Sleep’N Sync can be downloaded for $20, and the CD and book are priced at $36. Sleep’N Sync programs are available on www.sleepnsync.com, iTunes, and www.amazon.com.


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Disposable Timer May Reduce Workload Complexity for Nurses

The advance of technology translates into heavier, more complex workloads for nurses on the frontline of medical care. A simple, inexpensive, single-use timer from Dock Technologies may help ease the burden.

The disposable timer can be worn like a wristwatch and tells nurses when to administer a medication or unhook a medical device.

Dock Technologies has created prototypes of the timer, which wholesales for approximately $1, and is focusing on getting the timers manufactured.

The company is also working to refine the timer’s displays for maximum utility in specific uses, such as when medications must be delivered in a certain time window or when medical devices must be removed or changed at a specific time to avoid a hospital-acquired infection.


SUSTENNA was taken alone. The risk of relapse was approximately two times higher in the placebo group when INVEGA SUSTENNA was taken in combination with antidepressant or mood stabilizer treatment.

The risk in the placebo group was approximately three times higher for relapse due to any mood symptom; approximately four times higher for relapse due to manic symptoms; approximately three times higher for relapse due to depressive symptoms; approximately two times higher for relapse due to mixed symptoms; and approximately three times higher for relapse due to psychotic symptoms.

INVEGA SUSTENNA was superior to placebo in maintaining patient functioning as measured by the Personal and Social Performance (PSP) scale as a key secondary endpoint. A difference in PSP total score was observed in favor of INVEGA SUSTENNA (least squares mean [SE] 3.3 [1.33]; p = 0.014).

In the study, adverse events (AEs) occurring in more than 5% but less than 9% of patients in either group included weight gain, insomnia, worsening of schizoaffective disorder, headache, and nasopharyngitis. The most common movement disorders were akathisia and tremor. Thirteen percent of patients in the INVEGA SUSTENNA group and 6% in the placebo group experienced an approximately 7% increase in body weight. Potentially prolactin-related AEs were reported in 10.4% of patients in the INVEGA SUSTENNA group and 3.5% in the placebo group.

In related news, Janssen Pharmaceuticals, Inc. also announced the results of its Paliperidone Palmitate Research in Demonstrating Effectiveness (PRIDE) trial at the 167th Annual Meeting of the APA. The trial found that treatment with once-monthly INVEGA SUSTENNA significantly delayed time to relapse and reduced overall relapse in patients with schizophrenia compared with the most commonly used treatments.

The 15-month, multicenter, prospective, randomized, open-label, event monitoring board-blinded, active-controlled, U.S. study assessed the time to treatment failure, which is a subset of relapse, as its primary endpoint. The endpoint was defined as any one of the following: psychiatric hospitalization; arrest or incarceration; suicide; treatment supplementation or discontinuation of antipsychotic medication because of inadequate efficacy, safety concerns, or tolerability issues; or increased level of psychiatric services to prevent psychiatric hospitalization.

INVEGA SUSTENNA showed statistical superiority against the primary endpoint, delaying relapse in patients with schizophrenia and reducing overall relapse, as compared with the most commonly used treatments (i.e., daily oral antipsychotic agents). The risk of relapse was 1.4 times higher in the oral group than in the INVEGA SUSTENNA group.

No new safety issues were observed during the study. The most commonly observed issues were consistent with those listed in the current U.S. label, including injection site pain, insomnia, weight increase, akathisia, and anxiety.


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