Product Labeling Change Means More Dosing Options for Invega Sustenna

The U.S. Food and Drug Administration (FDA) has approved Janssen Pharmaceuticals, Inc.’s Supplemental New Drug Application for updated product labeling for Invega® Sustenna® (paliperidone palmitate). Invega Sustenna is a monthly extended-release injectable suspension atypical antipsychotic agent indicated for the treatment of schizophrenia. Among other changes, the approved labeling provides greater flexibility and dosing options for health care providers.

After the first initiation dose of Invega Sustenna, patients are given a second initiation dose 1 week later. Maintenance doses are then given once monthly. The updated product label includes additional instructions for appropriate alternatives to help avoid a missed dose when a patient cannot receive the second dose of Invega Sustenna when recommended.

To avoid a missed dose, patients may now be given the second initiation dose 4 days before or after the 1-week time point, instead of 2 days before or after the 1-week time point, as included in the original label.

Additionally, if the second Invega Sustenna initiation injection is completely missed, the recommended re-initiation depends on the length of time that has elapsed since the patient’s first injection.

Additional prescribing information revisions were also made to the Warnings and Precautions section. Dosage adjustment instructions have been added for when Invega Sustenna is co-administered with a strong CYP3A4 inducer (e.g., carbamazepine, rifampin, St. John’s wort). Additionally, information about the product’s Use in Specific Populations, notably nursing women and individuals with Parkinson’s disease or Lewy body dementia; and updates to the Boxed Warning and Indications and Usage have also been added. The revised label can be viewed in its entirety at http://www.InvegaSustenna.com/important-product-information.

Liquid Formulation of ADHD Drug Approved

NextWave Pharmaceuticals has announced the U.S. Food and Drug Administration approval of Quillivant XR™ (methylphenidate hydrochloride) for extended-release oral suspension, approved for the treatment of attention-deficit/hyperactivity disorder (ADHD). Quillivant XR, expected to become available in pharmacies in January 2013, is the first once-daily, extended-release liquid methylphenidate available for patients with ADHD, an option for those who have difficulty swallowing pills or capsules.

The efficacy of Quillivant XR was evaluated in a randomized, double-blind, placebo-controlled, crossover, multicenter, laboratory classroom study of 45 children with ADHD. There was an open-label dose optimization period (4 to 6 weeks) with an initial 20-mg dose of Quillivant XR once daily in the morning. The dose was titrated weekly in 10- or 20-mg increments until an optimal dose or maximum dose of 60 mg per day was reached. Patients then entered a 2-week double-blind, crossover treatment of the individually optimized dose of Quillivant XR or placebo.

At the end of each week, trained observers evaluated the attention and behavior of the patients in a laboratory classroom using the SKAMP (Swanson, Kotkin, Agler, M-Flynn, and Pelham) rating scale. Quillivant XR significantly improved ADHD symptoms compared with placebo at the primary endpoint of 4 hours post-dose, and in a secondary analysis, showed significant improvement at every time point measured, from 45 minutes to 12 hours after dosing.