FDA Approves RISPERDAL(R) for Treatment of Irritability Associated with Autistic Disorder

First Medication for Use in Children and Adolescents with Autism

TITUSVILLE, N.J., Oct. 6 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) today approved a new use of one of the leading prescription antipsychotic medications, RISPERDAL(R) (risperidone), for the treatment of irritability associated with autistic disorder, including symptoms of aggression, deliberate self-injury, temper tantrums, and quickly changing moods, in children and adolescents aged 5 to 16 years.(1) This is the first time the FDA has approved any medication for use in children and adolescents with autism.

"Autism is a complex disease," said James McCracken, M.D., director of the Division of Child and Adolescent Psychiatry at the Semel Institute for Neuroscience and Human Behavior at UCLA, a primary investigator and consultant to Janssen, L.P. "And while no one treatment is appropriate for all patients, in our studies we found that RISPERDAL(R) was highly effective in managing these severe and challenging behaviors often seen in children with autism."

Autism is usually diagnosed by age 3 and may affect 1 in 250 children.(2) The core symptoms of autism include communication deficits, impaired social interactions and stereotypic behaviors or interests. While RISPERDAL(R) does not treat these core symptoms, it has been shown to be beneficial in treating the associated behavioral disturbances that can interfere with school and learning, and family life.

"My daughter Jordan was so distressed that she would scream and cry for hours and hit herself repeatedly. We didn't know what to do, and it was a very dark time for our family," said Laura Condolora, the mother of an 11-year-old child with autism. "When Jordan started taking RISPERDAL(R), we began to see positive changes," said Mrs. Condolora. "Life was no longer a war between her and others. She seemed to let herself relax more."

While individual responses may vary, clinical studies found that patients with irritability associated with autistic disorder who received RISPERDAL(R) experienced significant behavioral symptom improvement versus those who were given placebo.(1)

The efficacy of RISPERDAL(R) in the treatment of irritability associated with autistic disorder was established in two eight-week, placebo-controlled trials in 156 children between the ages of 5 and 16 who met the DSM-IV criteria for autistic disorder.(1) Efficacy was evaluated using two assessment scales: the Aberrant Behavior Checklist (ABC) and the Clinical Global Impression -- Change (CGI-C) scale. The primary outcome measure in both trials was the change from baseline to endpoint in the Irritability subscale of the ABC (ABC-I). The ABC-I subscale measured the emotional and behavioral symptoms of autism, including aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods. The CGI-C rating at endpoint was a co-primary outcome measure in one of the studies and also showed significant improvement.

The dosage of RISPERDAL(R) should be individualized for children and adolescents based on weight. The safety and effectiveness of RISPERDAL(R) in pediatric patients with autistic disorder less than 5 years of age have not been established.

The most common adverse events with RISPERDAL(R) that occurred at an

incidence equal to or greater than 5% and at a rate of at least twice that of placebo include somnolence, increase in appetite, fatigue, upper respiratory tract infection, increase in saliva, constipation, dry mouth, tremor, muscle stiffness, dizziness, involuntary movements, repetitive behavior, rapid heart beat, confusion, and increase in weight.

RISPERDAL(R) is also approved in the U.S. to treat acute manic or mixed episodes of Bipolar I Disorder and for the treatment of schizophrenia in adults. It is marketed by Janssen, L.P.

RISPERDAL(R) (risperidone) is indicated for the treatment of irritability associated with autistic disorder in children and adolescents (ages 5-16 years), including symptoms of aggression towards others, deliberate self-injury, tantrums, and quickly changing moods.

RISPERDAL(R) (risperidone) is indicated for the treatment of schizophrenia and for the treatment of manic symptoms of acute manic or mixed episodes associated with bipolar I disorder.

IMPORTANT SAFETY INFORMATION

Elderly Patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.

RISPERDAL (risperidone) is not approved for the treatment of patients with Dementia-Related Psychosis.

Schizophrenia: The most common side effects that occurred with RISPERDAL were: anxiety, sleepiness, restlessness, tremors, and muscle stiffness; dizziness, constipation, nausea, indigestion, runny nose, rash, and rapid heartbeat.

Bipolar Mania: The most common side effects that occurred in clinical trials, in the treatment of bipolar mania either alone or in combination with a mood stabilizer (lithium or valproate) were: sleepiness, muscle stiffness, restlessness, tremor, indigestion, nausea, abnormal vision, muscle aches, dizziness, runny nose, diarrhea, increased saliva, stomach pain, and urinary incontinence.

Autistic Disorder: Sleepiness, increased appetite, fatigue, upper respiratory tract infection, increased saliva, constipation, dry mouth, tremor, muscle stiffness, dizziness, repetitive behavior, involuntary movement, rapid heartbeats, confusion, weight increase.

Studies suggest an increased risk of elevated blood sugar-related side effects, and sometimes potentially fatal, in patients treated with this class of medications, including RISPERDAL. Some people may need regular blood sugar testing.

You may have heard the term "tardive dyskinesia." These are usually persistent, uncontrollable, slow or jerky facial or body movements that can be caused by all medications of this type. If you have these symptoms, talk to your healthcare professional.

A rare but serious side effect that has been reported with this kind of medicine, including RISPERDAL, is known as neuroleptic malignant syndrome (NMS). NMS is characterized by muscle rigidity, fever and can be serious.

Some people taking RISPERDAL may feel faint or lightheaded when they stand up or sit up too quickly. By standing up or sitting up slowly and following your healthcare professional's dosing instructions, this side effect may be reduced or it may go away over time.

You may have heard the term "extrapyramidal symptoms" (EPS). These are usually persistent movement disorders or muscle disturbances, such as restlessness, tremors, and muscle stiffness. Some people taking RISPERDAL have these side effects. If you have these symptoms, talk to your healthcare professional.

Some medications interact with RISPERDAL. Please inform your healthcare professional of any medications or supplements that you are taking. Avoid alcohol while on RISPERDAL.

Inform your healthcare professional if you are already pregnant or if you are planning to get pregnant while taking RISPERDAL. Do not breast-feed if you are taking RISPERDAL.

RISPERDAL may affect your driving ability, therefore, do not drive or operate machines before talking to your healthcare professional.

RISPERDAL may affect alertness and motor skills; use caution until the effect of RISPERDAL is known.

Approved for marketing in more than 100 countries, RISPERDAL(R) is the most widely prescribed atypical antipsychotic in the world. Janssen, L.P. has marketed RISPERDAL(R) in the United States since 1994. It is given as an oral tablet, a quick-dissolve tablet or an oral solution. For full prescribing information, visit http://www.risperdalautism.com.

Based in Titusville, N.J., Janssen, L.P. currently markets prescription medications for the treatment of schizophrenia, bipolar disorder and irritability associated with autistic disorder. For full prescribing information, visit http://www.janssen.com.

(1) Final label.

(2) Bertrand J., Mars A., Boyle C., Bove F., Yeargin-Allsopp M., Decoufle P. Prevalence of autism in the United States population: the Brick Township, New Jersey, investigation. Pediatrics 2001; 108; 1155-61

SOURCE Janssen, L.P.