Strattera® Linked to Suicide Risk

The U.S. Food and Drug Administration (FDA) directed Eli Lilly and Company to revise the labeling on their Strattera® (atomoxetine) products to include additional warnings about an increased risk of suicidal thinking in children and adolescents treated with this drug. The increased risk for suicide ideation was identified in a combined analysis of 12 short-term, placebo-controlled trials, each lasting 6 to 18 weeks, and 11 of which included patients with attention-deficit/hyperactivity disorder (ADHD). The combined analysis included more than 2,200 patients, including 1,357 who took Strattera and 851 who took a placebo.

Analysis showed a greater risk of suicidal ideation during the first few months of treatment among patients who took Strattera, with an average risk of 4 patients per 1,000, compared to no patients who took placebo. One patient who took Strattera attempted suicide. The FDA has determined the following points should be included on Strattera labels:

- Strattera increases the risk of suicidal thinking in children and adolescents with ADHD.
- Health care providers considering using Strattera to treat children and adolescents with ADHD must balance the increased risk for suicidal thinking with the clinical need for the drug.
- Patients should be closely monitored for clinical worsening, suicidal thinking or behaviors, or unusual changes in behavior.
- Families and caregivers should be advised to closely observe patients for changes in behavior.


Study Compares Medications for Teens Addicted to Heroin

A study published in the Archives of General Psychiatry compared two drugs prescribed to treat adolescents dependent on heroin and other opioids. The study found that buprenorphine hydrochloride was more effective, especially in treatment retention, than clonidine hydrochloride.

The double-blind, randomized, controlled trial was conducted in an outpatient research clinic at the University of Vermont and included a sample of 36 opiate-dependent adolescents ages 13 to 18. Participants were randomly assigned to a 28-day, outpatient, medication-assisted withdrawal treatment using either buprenorphine or clonidine. Buprenorphine treats opiate addiction by preventing symptoms of withdrawal from heroin and other opiates, and clonidine belongs to a class of drugs known as alpha-blockers, which are commonly prescribed to treat high blood pressure.

Both agents were provided to participants along with behavioral counseling three times per week, as well as incentives contingent on opiate abstinence. Combining buprenorphine with behavioral intervention proved more effective than combining clonidine with behavioral interventions. The major difference

Possible New Medication for PMDD

A placebo-controlled clinical trial at New York-Presbyterian Hospital/Weill Cornell Medical Center is investigating the use of flutamide as a new drug therapy for premenstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome with debilitating symptoms including mood swings, intense anger, and impaired concentration. Currently, the only treatments approved for PMDD by the U.S. Food and Drug Administration (FDA) are selective serotonin reuptake inhibitors (SSRIs). However, 30% of women with PMDD do not respond to SSRIs, and an additional 20% cannot tolerate the side effects.

Flutamide, which is currently FDA-approved to treat prostate disease in men, reduces the activity of testosterone and other androgen hormones, which are known to promote irritability, a primary symptom of PMDD. In addition, androgens can cause fluid retention, impaired concentration, and mood swings.

The study is open to women ages 18 to 50 who are experiencing severe premenstrual mood symptoms. Participants will be randomized to regimens of either flutamide or placebo for 2 months, after which they will have the option of receiving a free 2-month treatment with an SSRI.

For more information, call 212-746-3759 or e-mail pmdd@med.cornell.edu.


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between the two medications was in treatment retention; over the course of a 28-day detoxification program, 72% of those who received buprenorphine were retained in treatment, while only 39% of those who received clonidine were retained.


FDA Links Birth Defects to Paxil®

Following a study looking at the link between the antidepressant agent Paxil® (paroxetine) and birth defects, the U.S. Food and Drug Administration (FDA) has requested GlaxoSmithKline change the labels of the medication. In addition, the FDA urged health care providers to inform their patients of the dangers and carefully weigh the potential risks and benefits of prescribing or renewing prescriptions for women of childbearing age.

The study, jointly conducted by the FDA and GlaxoSmithKline, reviewed the medical records of 3,581 infants born to women who took Paxil or other antidepressant agents during their first trimesters of pregnancy. Results suggested an increased risk of overall major congenital malformations and cardiovascular malformations, particularly ventricular septal defects, for paroxetine, compared to other antidepressant agents.

GlaxoSmithKline noted that the causal role of paroxetine remains unclear, as these and other recently published results contradict findings from previous large, epidemiological studies, including the Swedish Medical Birth Registry, which reported no increased risk for overall major malformations in infants born to women who took selective serotonin reuptake inhibitors, including paroxetine, early in their pregnancies.


Transition to Risperdal® Consta™ Improves Psychoses, Schizophrenia

According to a study conducted by Janssen-Cilag and published in International Clinical Psychopharmacology, patients with psychoses improved when their treatment was transitioned to Risperdal® Consta® (risperidone), a long-acting injection. Patients in the study were symptomatically stable but required a change of treatment in their existing antipsychotic regimens.

According to the authors, patients in the study experienced significant improvements in psychotic symptoms and satisfaction with treatment. Statistically significant improvements in symptoms were observed as early as 1 month after treatment, and continued to improve for the remaining 6 months of the study. Patient satisfaction also significantly improved; 31% of participants taking Risperdal Consta rated their treatment satisfaction as “very good,” up from 6% while on previous treatment.

The non-randomized, single-arm multicenter study assessed 1,876 patients in 22 countries. Approximately 38% of patients had a ≥20% improvement on their Positive and Negative Syndrome Scale total score, compared with baseline. Frequently reported adverse events included insomnia (7%), anxiety (7%), and exacerbation of disease (6%). In addition, some patients reported movement disorders (12%), but the percentage of patients reporting the onset of a movement disorder decreased from 4% in the first month to 1% during months 4 to 6 of the study.


Mirtazapine Now Available in Orally Disintegrating Tablets

TEVA Pharmaceuticals USA introduced Mirtazapine Orally Disintegrating Tablets, available in 15 mg, 30 mg, and 45 mg dosages in unit dosage blisters. The product is AB-rated and bioequivalent to Remeron SolTab®, which is approved by the U.S. Food and Drug Administration for the treatment of major depressive disorder in adults. Mirtazapine orally disintegrating tablets are rapidly and completely absorbed following oral administration and have a half-life of approximately 20 to 40 hours. Peak plasma concentrations are reached within approximately 2 hours following an oral dosage.

Do You Have Any Product News to Share? JPN would like to hear about it.

Please forward pertinent information to:

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