New Nonstimulant ADHD Drug Receives FDA Approvable Letter

Intuniv™ (guanfacine) extended-release tablets (previously referred to as SPD503) has received an approvable letter from the U.S. Food and Drug Administration (FDA). Intuniv is a once-daily, nonstimulant, selective alpha-2A-receptor agonist that has been studied in children and adolescents with attention-deficit/hyperactivity disorder (ADHD). The drug does not have a known mechanism for potential abuse or dependence and is not a controlled substance. When approved, it will be the first medication indicated for the treatment of ADHD symptoms by selective targeting of the alpha-2A receptors in the prefrontal cortex, where executive functioning tasks (e.g., working memory, behavioral inhibition, regulation of attention) are managed.

The Intuniv New Drug Application includes data from two placebo-controlled trials evaluating the drug’s safety and efficacy in controlling ADHD symptoms in children and adolescents ages 6 to 17, as evaluated once weekly using the ADHD Rating Scale (ADHD-RS-IV).


FDA Approves First Drug for Fibromyalgia

The U.S. Food and Drug Administration (FDA) has approved Lyrica® (pregabalin) for the treatment of fibromyalgia. Lyrica had been previously approved for treating partial seizures, pain following the rash of shingles, and pain associated with diabetic neuropathy. It is the first drug approved to treat fibromyalgia.

In two double-blind, controlled clinical trials involving approximately 1,800 patients with fibromyalgia, Lyrica was found to reduce pain and improve daily functioning at a dosage of 300 mg or 450 mg per day. However, the mechanism by which Lyrica produces such an effect is unknown.

The most common side effects reported in the trials were mild to moderate dizziness and sleepiness. Because Lyrica can impair motor function and cause problems with concentration and attention, the FDA advises patients to talk to their health care professional about whether its use may impair their ability to drive.


Once-Daily Seroquel XR Approved for Schizophrenia Treatment

The U.S. Food and Drug Administration (FDA) has approved Seroquel XR™ (quetiapine fumarate) once-daily extended-release tablets for the treatment of schizophrenia in adults. The drug was developed based on the need for a wider choice of medicines that offer convenient once-daily dosing. Patients taking Seroquel XR can achieve a dosage within the recommended range as early as the second day of treatment.

The FDA based its approval on results of a placebo-controlled study of 573 inpatients and outpatients experiencing acute exacerbation of symptoms of schizophrenia. The Positive and Negative Syndrome Scale was used to assess the effectiveness of Seroquel XR at dosages of 400 mg, 600 mg, and 800 mg per day. After 6 weeks of treatment, the total scores from baseline were significantly improved for those taking Seroquel XR compared with placebo.


Supplemental New Drug Applications for Risperdal Approved

The U.S. Food and Drug Administration (FDA) has granted an approvable letter for two supplemental New Drug Applications for Risperdal® (risperidone). The two applications are for the treat-
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ment of schizophrenia in adolescents ages 13 to 17, and for the short-term treatment of bipolar mania associated with bipolar I disorder in children and adolescents ages 10 to 17, respectively. The FDA has not requested additional studies.


Novel Noninvasive Device May Improve Depression Symptoms

According to data presented at the annual meeting of the American Psychiatric Association, NeuroStar® Transcranial Magnetic Stimulation (TMS) therapy significantly improved the quality of life and functioning of patients with moderate to severe depression who had not received adequate benefit from antidepressant therapy. NeuroStar TMS therapy is a noninvasive medical device being clinically studied in depression. The device works by delivering highly focused, strong magnetic field pulses that stimulate the brain nerve cells linked to depression. Because it does not require sedation or anesthesia, it can be administered as an outpatient procedure.

At baseline, the study population (N = 301) had significant symptomatic and functional impairment related to depression. After 4 weeks, patients receiving NeuroStar TMS therapy (n = 155) versus placebo experienced statistically significant improvements, as measured by the General Health and Mental Health subscales and the Mental Component Score of the SF-36. After 6 weeks, these patients experienced significant improvements on the SF-36 Role-Emotional subscale and the Quality of Life Enjoyment and Satisfaction Questionnaire.

A second, open-label trial evaluated the acute efficacy of NeuroStar TMS therapy administered as monotherapy in 158 patients for 6 weeks. At the end of the 6-week period, medication monotherapy was co-administered during a 3-week taper phase. Patients treated with NeuroStar TMS therapy experienced a significant improvement in

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Computerized Vest Monitors Mental Illness

Patterns of movements differ between patients with bipolar affective disorder and those with schizophrenia, according to a study using a novel device called a LifeShirt®—a computerized vest that continuously monitors hyperactive and repetitive movements and collects data on respiration, heart rate, and other physiological measures. The behavioral pattern monitor research, which was presented at the Society of Biological Psychiatry meeting, is based on parallel studies with rodents, which exhibited abnormal movement patterns and difficulties in filtering information when administered amphetamines or when genetic abnormalities that affect brain chemistry were present.

Patients’ movements while wearing the vest were characteristic of the manic phase of bipolar disorder. Patients with bipolar disorder exhibited hyperactivity and a wide range of exploration when in a novel environment, whereas the movements of patients with schizophrenia were much more restricted. It is sometimes difficult to diagnose whether an individual is exhibiting signs of schizophrenia or bipolar disorder. However, patients in the two study groups showed different patterns of exploration in new environments.

The research also aimed to determine how patients with bipolar disorder filter unimportant information from the environment; difficulty doing so may lead to the inappropriate behaviors that often occur during manic episodes. The researchers hope to discover new and improved drugs by comparing studies of the brain’s screening or filtering mechanisms in patients with mania before and after medication with observations of how rodents’ movement patterns are altered after taking medication. The collective findings could offer insight into the chemical imbalances and genetic abnormalities that contribute to bipolar disorder.


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Skin Patch for Early Parkinson’s Disease

A once-daily skin patch designed to treat symptoms of early Parkinson’s disease has received approval from the U.S. Food and Drug Administration, making Neupro® (rotigotine transdermal system) the first transdermal patch approved for treatment of Parkinson’s disease symptoms.

Rotigotine, a dopamine agonist agent not previously approved for use in the United States, is delivered continuously through the skin using a silicone-based patch that is replaced every 24 hours. The patch will be available in 2-mg, 4-mg, and 6-mg dosages.

The effectiveness of Neupro was demonstrated in one fixed-dose response study and two flexible-dose studies. The parallel group studies were randomized, double-blinded, and placebo-controlled and involved 1,154 patients with early Parkinson’s disease who were not taking other Parkinson’s medications.

The most common side effects for Neupro include skin reactions at the patch site, dizziness, nausea, vomiting, drowsiness, and insomnia. Other potential safety concerns include sudden onset of sleep while engaged in routine activities (e.g., driving, operating machinery), hallucinations, and decreased blood pressure after standing up.


Strattera Effective for Patients with ADHD and Alcohol Abuse

Results of a 12-week clinical study suggest attention-deficit/hyperactivity disorder (ADHD) can be treated safely and effectively with Strattera® (atomoxetine HCl) in patients with comorbid alcohol abuse disorder.

The study included 147 adults with ADHD and comorbid alcohol abuse. Study participants were recently abstinent from alcohol at least 4 days before study randomization and included 125 men and 22 women, with a mean age of 34.

For 12 weeks, 72 participants received 25 mg to 100 mg of Strattera daily and 75 received placebo. Strattera was found to be superior to placebo in reducing ADHD symptoms, as measured by the ADHD Investigator Symptom Rating Scale. At the end of the study, symptoms had significantly improved for the Strattera group (–13.63) versus the placebo group (–8.31). No significant difference was found between the groups in the time to alcohol abuse relapse, defined as four standard alcoholic drinks for women and five for men within 24 hours, or at least three drinks per day for at least 1 week. Results also revealed a positive trend in reducing cumulative heavy drinking days by 26% in the Strattera group compared with the placebo group. Discontinuation rates due to adverse events were 9.7% for the Strattera group, compared with 2.7% for the placebo group.