Addyi™ Approved to Treat Hypoactive Sexual Desire Disorder

Sprout Pharmaceuticals, Inc., announced that the U.S. Food and Drug Administration (FDA) granted approval of Addyi™ (flibanserin 100 mg), a once-daily, nonhormonal pill for the treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women. Addyi is the first and only FDA-approved treatment for this condition, the most common form of female sexual dysfunction affecting one in 10 women in the United States.

FDA approval of Addyi is largely based on three North American, Phase 3, 24-week, randomized double-blind, placebo-controlled studies of premenopausal women with HSDD. Addyi demonstrated improvements in desire for sex, reducing distress from the loss of sexual desire, and increasing the number of satisfying sexual events. Addyi was administered to >2,500 premenopausal women with acquired, generalized HSDD in clinical trials, with >850 receiving treatment for at least 12 months.

Sprout Pharmaceuticals has committed to enhanced pharmacovigilance and Phase 4 studies to mitigate and further characterize the safety profile of Addyi.

doi:10.3928/02793695-20151021-44

Cognizin® Citicoline Can Help Reduce Cocaine Use

Results of a randomized, double-blind, placebo-controlled clinical trial showed that Cognizin® citicoline was effective at reducing cocaine use, based on urine drug screens, in patients with bipolar disorder and cocaine dependence. The study included a total of 130 outpatients with bipolar I disorder and cocaine dependence, who received either Cognizin citicoline or placebo add-on therapy for 12 weeks.

In the study, placebo and citicoline groups submitted to three weekly urine drug screens. Mood was assessed by the Inventory of Depressive Symptomatology-Self Report, Hamilton Depression Rating Scale, and Young Mania Rating Scale.

The citicoline group saw no significant group differences in manic or depressive symptoms following supplementation. At the same time, Cognizin citicoline decreased cocaine use without impacting mood, meaning the efficacy of citicoline for reducing cocaine use not only holds promise as a treatment in this population, but could potentially hold true for other patients.