Addition of Lyrica Significantly Improved Generalized Anxiety Disorder Symptoms in Patients Who Responded Only Partially to Previous GAD Treatments

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First Large, Placebo-Controlled Study to Demonstrate Efficacy of Lyrica as Add-on Therapy Strategy in Difficult-to-Treat GAD Patients

(BUSINESS WIRE)--The addition of Pfizer's Lyrica® (pregabalin) capsules CV to other generalized anxiety disorder (GAD) treatments significantly improved the symptoms of the condition in patients who responded only partially to previous treatments, according to a study presented today at the American Psychiatric Association annual meeting in San Francisco, Ca. In this study, patients treated with Lyrica showed significant improvements in both their psychological and physical symptoms of anxiety.

Generalized anxiety disorder is a chronic, debilitating anxiety disorder affecting nearly seven million Americans and is characterized by persistent, excessive, uncontrollable worry about everyday things. Patients also frequently experience physical symptoms such as muscle tension, fatigue, sleep disturbance, and other aches and pains.

The condition is complex and often difficult to treat, with 40 percent to 60 percent of patients failing to achieve remission after six months of treatment in clinical studies with serontonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs) - two common classes of FDA-approved GAD treatments.

“These data are very encouraging for the high percentage of GAD patients who still struggle with debilitating symptoms despite treatment,” said Dr. Rakesh Jain, one of the study’s investigators and director, adult and child psycho-pharmacology research, R/D Clinical Research, Inc. “It is clear we need additional effective, well-tolerated options to address this difficult to treat condition.”

This is the first large, placebo-controlled trial to demonstrate the efficacy of an add-on therapy strategy in patients who had failed to respond to two different courses of GAD monotherapy with a SSRI, SNRI or benzodiazepine.

The study found that patients treated with Lyrica in addition to their baseline SSRI/SNRI therapy had a significantly greater improvement in overall anxiety symptoms as well as individual psychological and physical symptoms compared to baseline therapy alone as measured by the Hamilton Anxiety Scale (HAM-A), an interview scale that measures the severity of a patient's anxiety. Over the eight week treatment period, patients receiving add-on Lyrica therapy had, on average, an anxiety score that was 1.2 points lower on the HAM-A compared to baseline therapy alone (P=0.012).

Significantly more patients receiving add-on Lyrica treatment (50 percent) showed at least a 50 percent reduction in their anxiety symptoms compared to SSRI/SNRI treatment alone (37 percent) (P=0.023). Lyrica was also shown to be well tolerated as an add-on therapy in this study.

About the Study

This study was a double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy and safety of adjunctive Lyrica in 353 patients with a primary diagnosis of GAD. To be included in the study, patients had to have a HAM-A score greater or equal to 22, and to have not responded, or only minimally responded, to treatment with a SSRI, SNRI or benzodiazepine prior to the study.

These patients were then treated with a different SSRI/SNRI for eight weeks. At the end of the eight week open-label treatment period, patients who had shown only a partial response to treatment (as defined by a HAM-A score of greater than or equal to 16, less than 50 percent decrease in HAM-A score, and a Clinical Global Impression Improvement score of less than 3) were then randomized to an additional eight weeks of double-blind treatment with either Lyrica (150 to 600 mg/day) or placebo while continuing treatment with the existing background SSRI or SNRI therapy.

The primary endpoint was the mean change score on the Hamilton Anxiety Rating Scale. The SSRIs and SNRIs used in this study included escitalopram, paroxetine and venlafaxine XR.

The most common side effects in the study compared to other GAD treatments plus placebo were dizziness (11.7 percent vs. 5.7 percent), headache (9.4 percent vs. 4 percent), and somnolence (8.3 percent vs. 3.4 percent).

This study was sponsored by Pfizer, Inc.

About Lyrica

In the United States, Lyrica is approved for the management of fibromyalgia, painful diabetic peripheral neuropathy, postherpetic neuralgia (pain after shingles), and for the adjunctive treatment of partial onset seizures (a type of epilepsy) in adults. Lyrica is not approved for GAD in the U.S.

Outside of the United States, Lyrica is indicated in adults for the management of peripheral and central neuropathic pain, treatment of generalized anxiety disorder, and adjunctive therapy for partial seizures with or without secondary generalization.

Important Safety Information

Treatment with Lyrica may cause dizziness, somnolence, peripheral edema or blurred vision. Other most common adverse reactions include dry mouth, weight gain, constipation, euphoric mood, balance disorder, increased appetite and thinking abnormally. There have been post-marketing reports of angioedema and hypersensitivity. Like other anti-epileptic drugs, Lyrica may cause suicidal thoughts or actions in a very small number of people.

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DISCLOSURE NOTICE: The information contained in this release is as of May 19, 2009. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about the use of Lyrica for GAD, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by the Food and Drug Administration (FDA) regarding whether and when to approve any supplemental drug application that may be filed for a GAD indication for Lyrica as well as the FDA’s decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K.

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