Lyrica Reduced Pain of Fibromyalgia in Patients Regardless of Symptoms of Anxiety or Depression

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Patient Reports of Improvement Linked to Reduction in Pain and Enhanced Sleep

(BUSINESS WIRE)--Pfizer's Lyrica reduced pain of fibromyalgia in patients regardless of whether they experienced symptoms of anxiety or depression at the beginning of the study, according to a pooled analysis presented today at the American Academy of Neurology annual meeting. The analysis, which looked at data pooled from previous clinical trials, also showed that patients' self-reported improvements were more closely associated with improvements in pain and sleep than with improvements in fatigue or symptoms of anxiety or depression.

Fibromyalgia is the most common, chronic widespread pain condition in the United States and is thought to result from neurological changes in how patients perceive pain. Fibromyalgia is usually accompanied by poor sleep, stiffness and fatigue.

"The data showed that Lyrica reduced fibromyalgia pain, and alleviating that pain was associated with patients' overall feeling of well-being," said Dr. Lesley Arnold, one of the study's authors and associate professor in the department of psychiatry at the University of Cincinnati Medical Center. "Understandably, many patients with a chronic pain condition such as fibromyalgia also experience depression and anxiety, and importantly we found that Lyrica helped reduce pain in patients regardless of the presence of symptoms of these co-morbid conditions."

About the Analysis

The results are from a retrospective, pooled analysis of data from three placebo-controlled clinical trials (8 weeks, 13 weeks and 14 weeks long) of Lyrica in over 2,000 fibromyalgia patients. These studies randomized patients to receive Lyrica 150 mg, 300 mg, 450 mg or 600 mg or placebo. Patients were asked to measure their pain on a scale of zero to 10; the baseline score for study participants was 6.9 (150 mg, 450 mg, 600 mg) or 7.0 (300 mg). A score of 4.0 to 6.9 is considered moderate pain and a score of greater than 7.0 is considered moderate to severe pain on this 10-point scale.

In the studies, 38 percent of fibromyalgia patients had moderate to severe anxiety symptoms, while 27 percent had moderate to severe depressive symptoms, as assessed using the Hospital Anxiety and Depression Scales (HADS-A or HADS-D). Patients with severe depression or unstable psychiatric conditions were excluded from the studies.

The new analysis confirmed that Lyrica was significantly more effective than placebo in reducing pain in patients with fibromyalgia. Patients receiving 600 mg a day of Lyrica had a pain reduction of 2.08 on the pain scale; 450 mg a day had a reduction of 2.01; 300 mg a day had a reduction of 1.76; 150 mg a day had a reduction of 1.37, and placebo had a reduction of 1.25. Additionally, Lyrica was found to reduce pain in patients regardless of whether they had symptoms of anxiety or depression.

The analysis also examined the relationship between improvements in pain, sleep, fatigue, anxiety and depressive symptoms with patients reporting feeling “much improved” or “very much improved” as measured by the Patient Global Impression of Change (PGIC). The PGIC is a standardized, self-reported tool that measures the change in a patient’s overall status ranging from “very much improved” to “very much worse.”

Pain reduction was found to have the greatest association on patients reporting improvement as measured by PGIC. The relationships between feeling much or very much improved were strongest for pain and sleep, and less pronounced for fatigue and symptoms of anxiety or depression, but statistically significant for all variables.

The most common side effects in the pooled analysis versus placebo of these three studies were dizziness and somnolence, followed by weight gain, blurred vision and dry mouth.

About Lyrica

In the United States, Lyrica® (pregabalin) capsules, CV, is approved for the management of fibromyalgia. Lyrica is also indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia (pain after

shingles), and as adjunctive therapy for adults with partial onset seizures. The 600 mg/day is not an approved dosage for Lyrica in the management of fibromyalgia.

Important Safety Information

Lyrica is not for everyone. Lyrica may cause serious allergic reactions. Patients should tell their doctors right away about any serious allergic reaction such as swelling of the face, mouth, lips, gums, tongue or neck or if they have any trouble breathing. Other allergic reactions may include rash, hives and blisters. Patients should tell their doctors about any changes in eyesight, including blurry vision, muscle pain along with a fever or tired feeling, or skin sores due to diabetes.

Some of the most common side effects of Lyrica are dizziness, sleepiness, weight gain, blurred vision, dry mouth, feeling "high", swelling of hands and feet, and trouble concentrating. Patients may have a higher chance for swelling and hives if they are also taking angiotensin converting enzyme (ACE) inhibitors so they should let their doctors know if they are taking these medications. They may have a higher chance of swelling or gaining weight if they are also taking certain diabetes medicines.

Patients should not drive a car or operate machinery until they know how Lyrica affects them. Patients should not drink alcohol while on Lyrica. Patients should be especially careful about medicines that make them sleepy and should also tell their doctors if they are planning to father a child. Patients should tell their doctor if they are pregnant, plan to become pregnant, or are breast-feeding. If they have had a drug or alcohol problem, they may be more likely to misuse Lyrica. Patients should talk with their doctor before they stop taking Lyrica, or any other prescription medication. Lyrica is one of several treatment options for doctors to consider.

For Lyrica prescribing information, please visit www.lyrica.com.

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