Pfizer's Lyrica Receives FDA Approval for Fibromyalgia Based on Expedited Review

Thursday, June 21, 2007 - 02:33am

First FDA-Approved Medicine for Fibromyalgia Represents Treatment Advance for Millions of Americans Suffering From This Chronic, Widespread Pain Condition

(BUSINESS WIRE)--Pfizer announced today that the Food and Drug Administration (FDA) approved Lyrica® (pregabalin) capsules CV for the management of fibromyalgia, one of the most common chronic, widespread pain conditions in the United States. The approval of Lyrica, which received a priority review, represents a breakthrough for the more than six million Americans who suffer from this debilitating condition who previously had no FDA approved treatment options.

“This is an important day for people with fibromyalgia and a real opportunity to help physicians effectively manage this disorder,” said Dr. Don Goldenberg, M.D., co-chair of the fibromyalgia guideline panel for the American Pain Society and professor of medicine, Tufts University. "Having a medication approved for use in fibromyalgia, along with research advances, will go a long way to improving our understanding and treatment of this common disorder."

Characterized by chronic widespread pain that can be relentless, fibromyalgia is usually accompanied by poor sleep, stiffness and fatigue; sufferers also report experiencing deep tenderness, soreness and flu-like aching. The pain of fibromyalgia can hamper a patient’s ability to work and often results in increased medical costs and disability.

“I had to give up my career and I wasn’t able to participate in a lot of my children’s activities,” said Carolyn Bishop, a fibromyalgia patient and participant in one of the Lyrica clinical trials.

Fibromyalgia is thought to result from neurological changes in how patients perceive pain, specifically a heightened sensitivity to stimuli that are not normally painful. Lyrica binds to a specific protein within overexcited nerve cells and works to calm damaged nerves. This is thought to reduce the level of pain in patients suffering from fibromyalgia, although the exact mechanism of how Lyrica acts in fibromyalgia is not known.

“Since I’ve started taking Lyrica, I’ve had less pain and felt better,” added Carolyn Bishop.

Lyrica’s approval for fibromyalgia represents the eighth Pfizer treatment to receive “ priority review” status from the FDA over the past two and a half years. In addition to Lyrica’s initial approval for the management of neuropathic pain associated with diabetic peripheral neuropathy, other priority reviews included Sutent for advanced kidney cancer and gastrointestinal stromal tumors and Chantix for smoking cessation.

“Pfizer undertook a robust clinical development program to evaluate Lyrica’s effectiveness in treating a number of conditions where there is a huge unmet medical need,” said Joe Feczko, Pfizer’s chief medical officer. “We are now seeing the dividends from our comprehensive research investment in the value that Lyrica will bring to patients suffering from fibromyalgia.”

In the clinical trials, Lyrica demonstrated rapid and sustained improvements in pain compared with placebo. In addition, patients taking Lyrica reported feeling better and improvements in physical function.

About Lyrica

Lyrica has been prescribed to more than five million patients worldwide.

In addition to this new indication in the United States, Lyrica is approved for the management of neuropathic pain associated with diabetic peripheral neuropathy and post-herpetic neuralgia, and for the adjunctive therapy for adult patients with partial onset seizures.

The most common side effects occurring during the clinical trials for patients taking Lyrica versus those taking placebo were dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, constipation, euphoric mood, balance disorder, increased appetite and thinking abnormally (primarily difficulty with concentration/attention).

Lyrica may cause allergic reactions such as angioedema and hypersensitivity. Some reported allergic reactions include swelling of the face, mouth, lips, gums, tongue, neck

and trouble breathing. Others may include rash, hives and blisters. Patients should be instructed to discontinue Lyrica and seek immediate medical care if they experience these symptoms.

Patients taking Lyrica should be counseled that dizziness and somnolence may impair their ability to perform potentially hazardous tasks such as driving or operating complex machinery until they have sufficient experience with Lyrica to determine its effect on cognitive and motor function.

In all controlled studies, a higher proportion of patients treated with Lyrica reported blurred vision (7%) than did patients treated with placebo (2%), which resolved in a majority of cases with continued dosing. More frequent assessment should be considered for patients who are already routinely monitored for ocular conditions. If patients have had a drug or alcohol problem, they may be more likely to misuse Lyrica.

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

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