Lyrica Significantly Reduced Pain and Helped Patients Manage the Symptoms of Fibromyalgia, Data Show

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Lyrica is First Treatment Under FDA Review for Fibromyalgia, Which Affects More than Six Million Americans

(BUSINESS WIRE)--Significantly more patients treated with Pfizer's Lyrica reduced their pain by 50 percent or more compared with placebo, according to study results presented today at the American Academy of Neurology annual meeting. Clinically, this outcome would equate to a patient with severe pain reporting a reduction to mild to moderate pain.

Fibromyalgia is one of the most common chronic, widespread pain conditions and is thought to result from neurological changes in how patients perceive pain. Fibromyalgia is usually accompanied by poor sleep, stiffness and fatigue. The pain of fibromyalgia can hamper a patient's ability to work and often results in increased medical costs and disability. There are no medications approved to treat fibromyalgia.

"A growing body of evidence is defining the biology behind fibromyalgia that causes such devastating and constant pain," said Dr. I. Jon Russell, one of the study's authors and associate professor of medicine in the division of clinical immunology and rheumatology and director of the university clinical research center at the University of Texas Health Science Center, San Antonio. "A reduction in pain is critical for people living with this condition. With positive new data and new treatments on the horizon, the outlook for people with fibromyalgia has never been better."

The 14-week placebo-controlled study included 745 patients with fibromyalgia who were randomized to receive Lyrica (300mg, 450mg or 600mg) or placebo daily. Patients were asked to measure their pain on a scale of zero to 10; the baseline score for study participants was 6.7 on this 10-point scale.

The study found that patients receiving 600mg a day of Lyrica reduced their pain by 2.05 on the pain scale; 2.03 for patients taking 450mg a day; 1.75 for patients taking 300mg a day, and 1.04 for patients taking placebo.

Significantly more patients treated with Lyrica reduced their pain by 50 percent or more compared with placebo. Of those patients taking 600mg of Lyrica a day, 30 percent said their pain was cut in half or better; 27 percent of those taking 450mg a day and 24 percent of those taking 300mg also reported this level of pain relief. Of those taking placebo, 15 percent reported pain reduction of 50 percent or greater.

Patients receiving Lyrica also reported significant improvements in overall health status and outcomes, including measures such as physical function and ability to perform everyday tasks.

The most common side effects in the study were dizziness and somnolence, followed by weight gain, headache and peripheral edema.

The results of these data were submitted to the FDA as part of a supplemental New Drug Application for Lyrica for the treatment of fibromyalgia. Pfizer also intends to pursue a fibromyalgia indication in other major markets worldwide.

About Lyrica

To date, more than five million patients worldwide have used Lyrica.

In the United States, Lyrica (pregabalin) capsules CV is approved for the management of neuropathic pain associated with diabetic peripheral neuropathy and post-herpetic neuralgia, and in epilepsy for the adjunctive treatment of partial onset seizures in adults.

Outside of the United States, Lyrica is approved for use in adults for the treatment of various peripheral and central neuropathic pain indications, including diabetic pain and post-herpetic neuralgia, pain resulting from spinal cord injury, and adjunctive therapy for partial seizures in more than 60 countries. In 2006, Lyrica was also approved in Europe for the treatment of generalized anxiety disorder.

DISCLOSURE NOTICE: The information contained in this release is as of May 1, 2007. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties regarding a potential additional indication for Lyrica that is under review by the Food and Drug Administration (FDA). Such risks and uncertainties include, among other things, whether and when the FDA and regulatory authorities in other countries will approve supplemental new drug applications for this additional indication and their decisions regarding labeling and other matters that could affect its availability or commercial potential, as well as competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and in its reports on Form 10-Q and Form 8-K.

Pfizer Jack Cox, 212/733-5017 or Stephen Borboroglu, 212/733-1787 Onsite: 917/622-8724