

PFIZER'S PREGABALIN SIGNIFICANTLY IMPROVES PAIN IN FIBROMYALGIA PATIENTS, NEW DATA SHOW

No Therapies Approved for Chronic Pain Associated with Fibromyalgia; Poor Sleep and Fatigue Also Characterize Condition

NEW ORLEANS, October 26, 2002 -- Pfizer Inc's pregabalin was shown to provide improvement of pain in patients with fibromyalgia, a chronic and debilitating pain syndrome, according to data presented here today at the annual meeting of the American College of Rheumatology.

Pregabalin also was shown to improve sleep and fatigue levels, the data demonstrate.

Fibromyalgia syndrome (FMS) is a chronic disorder characterized by widespread musculoskeletal pain that is frequently associated with fatigue and sleep disturbances. It is estimated to affect two percent of the population, or 5.6 million Americans, and occurs most frequently in women.

The double-blind, placebo-controlled monotherapy study involved 529 patients diagnosed with FMS. Patients were randomized to receive placebo or pregabalin (150 mg, 300 mg or 450 mg per day) for eight weeks. The study evaluated the efficacy and safety of pregabalin for the treatment of pain and associated symptoms such as sleep and fatigue. Patients were required to characterize and record their pain on a daily basis in detailed diaries.

Pregabalin-treated patients (450 mg/day) showed statistically significant improvements in pain compared to those who received placebo. Further, 29 percent of pregabalin-treated patients reported at least a 50 percent reduction in pain, compared with a reduction of 13 percent for patients who received placebo, a difference that was statistically significant. In addition, pregabalin significantly improved sleep quality and fatigue.

"To demonstrate improvements in the core symptoms of FMS—pain, sleep and fatigue—represents an important advance, particularly as there are no approved treatments for this condition," said Dr. Leslie Crofford, lead investigator and associate professor of internal medicine, Division of Rheumatology, at the University of Michigan in Ann Arbor.

"FMS is highly debilitating for patients and difficult to treat, and we are in need of new treatment options that are both effective and well tolerated," Dr. Crofford said. "These data are highly encouraging because pregabalin was shown to provide significant relief from the most troublesome symptoms for patients."

The most common dose-related side effects reported by patients were dizziness and drowsiness. Most adverse events were mild to moderate in intensity, and many resolved during the study. Seventy-eight percent of all patients completed the study.

Developed by Pfizer, pregabalin has been studied in an extensive clinical program involving over 8,000 patients worldwide. The company has completed pivotal studies to support the filing of a New Drug Application for pregabalin for the treatment of neuropathic pain and generalized anxiety disorder and as an add-on therapy for epilepsy.

Pfizer Neuroscience is committed to pioneering innovative therapies for neurological and psychiatric disorders. Pfizer's experience in the areas of depression, anxiety, schizophrenia, Alzheimer's disease and epilepsy has helped bring leading medicines to market for the treatment of these disorders.

Neurological and psychiatric disorders represent an important priority in Pfizer's \$5.2 billion development effort, with more than 20 percent of the company's research and development budget allocated to finding more effective neuroscience medicines for mood and anxiety disorders, migraine, pain, epilepsy and smoking cessation.

Pfizer Inc discovers, develops, manufactures and markets leading prescription medicines for humans and animals and many of the world's best-known consumer brands.