



Pfizer Exploratory Study Measures Effects Of Lyrica (pregabalin) On Brain Activity In Fibromyalgia Patients

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First fMRI Data in Fibromyalgia Among Lyrica Presentations at APS Meeting

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today the results of studies on Lyrica® (pregabalin) capsules CV presented at the American Pain Society Annual Meeting in Honolulu. The studies included exploratory research designed to provide new insight into how Lyrica works in the brains of patients with fibromyalgia. A total of seven Lyrica abstracts were presented.

Pfizer and study investigators presented three abstracts from the first study to use functional magnetic resonance imaging (fMRI) to measure the effects of Lyrica on brain activity in fibromyalgia patients. In this exploratory study, Lyrica decreased connectivity between various parts of the brain involved in pain processing, an important effect considering that fibromyalgia patients have elevated intrinsic connectivity. Additionally, the fMRI study suggested Lyrica reduced visual activation or sensory stimulation that activates pain and affects related brain regions in fibromyalgia patients. In an additional fMRI analysis, Lyrica was found to affect grey matter density in parts of the brain known to process pain. In this study, the most common adverse event in Lyrica-treated patients was dizziness when compared with placebo. The adverse event profile is consistent with that known for Lyrica.

It has been hypothesized that the central nervous system (CNS) in patients with fibromyalgia is hyper-sensitive to pain signals. These are the first exploratory data using fMRI and Lyrica that suggests an association between treatment and changes in central pain processing pathways in FM patients.

“This is the first exploratory fMRI study to investigate the mechanism of action of Lyrica in humans with fibromyalgia,” said study investigator Richard E. Harris, Ph.D., Assistant Professor, Department of Anesthesiology and Research Assistant Professor, Department of Internal Medicine, University of Michigan. “This exploratory study not only shows how fibromyalgia affects the brain, it provides further insights on how Lyrica may impact central pain processing pathways in the brain.”

Additional fMRI Study Details

The fMRI data, which were presented in multiple sessions, come from an exploratory double-blind crossover study of 17 women who were given either Lyrica (150-450 mg/day) or a placebo for 14 days, then, after a washout period, crossed over to the opposite group. Before and after each treatment period, functional MRI images were taken while the patients received blunt pressure pain to measure activity in the brain.

Pfizer previously reported other results from this study which showed that Lyrica reduced glutamate in fibromyalgia patients in areas of the CNS associated with pain processing.

“These data demonstrate Pfizer’s commitment to enhancing the scientific community’s understanding of Lyrica,” said Steven J. Romano, M.D., senior vice president, Head, Medicines Development Group, Global Primary Care Business Unit, Pfizer, Inc. “By using technologies such as fMRI, we can contribute to a growing body of research in pain physiology with the goal of answering patient needs in a more meaningful way.”

About Lyrica

Lyrica® is currently approved in 110 countries and regions globally. In the United States, Lyrica (pregabalin) capsules CV are indicated for neuropathic pain associated with diabetic nerve pain, post herpetic neuralgia (pain after shingles), fibromyalgia and partial onset seizures in adults with epilepsy who take one or more drugs for seizures. Antiepileptic drugs (AEDs) including Lyrica increase the risk of suicidal thoughts or behavior in patients taking AEDs for any indication. There have been post-marketing reports of angioedema and hypersensitivity with Lyrica. Treatment with Lyrica may cause dizziness, somnolence, dry mouth, edema and blurred vision. Other most common adverse reactions include weight gain, constipation, euphoric mood, balance disorder,

increased appetite and thinking abnormal (primarily difficulty with concentration/attention.)

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

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