# Pfizer Reports Top-Line Results Of A Phase 3 Study Evaluating Pregabalin Controlled-Release Formulation As Adjunctive Treatment In Adult Patients With Partial Onset Seizures

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced top-line results of a double-blind, placebo-controlled, Phase 3 study evaluating both the 165 mg dose and the 330 mg dose of pregabalin controlled-release (CR) formulation in adult patients with partial onset seizures with epilepsy. These study results indicate pregabalin CR did not meet its primary endpoint comparing the change in seizure frequency to placebo, although both doses were well-tolerated.

This study is one of three Phase 3 studies of the pregabalin CR formulation, which will ascertain the potential use of pregabalin as a once-a-day therapy. The other two studies are evaluating the pregabalin CR formulation in fibromyalgia and post-herpetic neuralgia. Pfizer will continue to further analyze these top-line results as well as the top-line results of the other two studies.

"While the study showed an observed improvement, it did not show a statistically significant difference in seizure frequency, which we believe may have been due to a higher-than-expected placebo response," said Steven J. Romano, M.D., senior vice president, head, Medicines Development Group, Global Primary Care Business Unit, Pfizer

Inc. "Lyrica immediate-release has a proven success record in patients with epilepsy, and we look forward to understanding further the potential role of a once-a-day pregabalin formulation."

Epilepsy is a chronic disorder in which seizures occur intermittently. Partial onset seizures (simple, complex, and secondarily generalized tonic-clonic) are the most common. In the U.S., the immediate-release formulation – Lyrica® (pregabalin) capsules CV has been used as adjunctive therapy for partial onset seizures since its approval in June 2005.

About the Study

The objective of the double-blind, randomized, parallel group, multi-center study was to assess the efficacy and safety of pregabalin CR as adjunctive treatment of partial onset seizures in adult patients with epilepsy.

The study was conducted in a total of 18 countries at 66 sites. The study included four phases: Phase 1 - an 8 week baseline phase during which the baseline seizure rate was recorded; Phase 2 - a 2 week double-blind dose escalation phase; Phase 3 - a 12 week double blind maintenance phase where the dosage of study medication was fixed; and Phase 4 - a 1 week taper phase at the conclusion of the study. Treatment groups included pregabalin CR 165 mg/day, pregabalin CR 330 mg/day or placebo at a 1:1:1 ratio. These pregabalin CR dose levels provided exposure similar to 150 mg and 300 mg daily doses of currently available Lyrica (pregabalin) immediate-release formulations.

The primary endpoint was the loge-transformed 28 day seizure rate for all partial onset seizures collected during the double-blind treatment phase compared to the 8 week baseline (screening) seizure period.

The analysis of the primary endpoint, loge (28-days seizure rate + 1), showed a non-significant result between pregabalin and placebo for the pregabalin CR 330 mg group ($p=0.0907$). Responder rates, defined as the percentage of patients with a $\geq 50\%$ reduction in seizure frequency from baseline, were 45.9%, 37.8% and 35.8% for the CR 330 mg, CR 165 mg, and placebo groups, respectively, and highlight the high placebo response observed in this study.

Both pregabalin CR 330 mg and pregabalin CR 165 mg were well tolerated in this population. The tolerability and safety findings are consistent with past pregabalin findings for patients with epilepsy, with dizziness, weight increased and somnolence as the most frequently reported adverse events in the study.

About Lyrica

Lyrica® is currently approved for various indications in 120 countries and regions globally. Since its first approval from the FDA in 2004, Lyrica has been approved for five indications in the U.S., of which four are in the therapeutic area of pain. These indications include neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia (pain after shingles), neuropathic pain associated with spinal cord injury, 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 in the United States, please visit www.lyrica.com.

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DISCLOSURE NOTICE: The information contained in this release is as of November 16, 2012. 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 about a potential additional indication for Lyrica as a once-a-day treatment, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any supplemental drug applications that may be filed for such additional indication as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q and Form 8-K.

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