



# Pfizer Reports Top-Line Results Of A Phase 3 Study Evaluating Pregabalin Controlled-Release As Treatment For Patients With Fibromyalgia

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced that top-line results of a double-blind, Phase 3 study evaluating pregabalin controlled-release (CR) formulation in patients with fibromyalgia indicate that pregabalin CR had a statistically significant positive effect compared to placebo in the primary endpoint, time to loss of therapeutic response (LTR). Fibromyalgia is a common pain condition in the United States, affecting more than five million Americans. It is characterized by chronic widespread pain and tenderness lasting for three or more months.

This study is the second of three Phase 3 studies of the pregabalin CR formulation to report top-line findings, which will ascertain the potential use of pregabalin as a once-a-day therapy. The top-line results of the first study in adults with partial onset seizures with epilepsy did not meet its primary endpoint. The final study in post-herpetic neuralgia is ongoing. Pfizer will analyze further results of all three studies once data are available.

"Collectively, the results of these controlled release studies will allow us to better understand the potential of a once-a-day pregabalin treatment regimen," said Steven J. Romano, M.D., senior vice president, head, Medicines Development Group, Global Primary Care Business Unit, Pfizer Inc. "Reducing the number of times patients need to take their medicine per day while maintaining the same efficacy and safety profile could potentially provide a greater convenience and the potential to enhance treatment adherence and outcomes."

## About the Study

The objective of the double-blind, placebo-controlled, multi-center, randomized withdrawal study was to assess the efficacy and safety of pregabalin CR as treatment for patients with fibromyalgia.

The study was composed of 4 phases: baseline (1 week), single-blind (SB) treatment (6 weeks), double-blind (DB) treatment (13 weeks), and a 1-week double-blind taper. Study medication was administered once daily (QD) immediately following the evening meal. During the SB phase, an optimal dose of pregabalin CR (between 300 mg/day to 495 mg/day) was determined. In the DB phase, patients were randomized to continued pregabalin CR treatment at the optimized dose or to matching placebo.

A total of 441 subjects were enrolled into the SB phase from 49 sites in 4 countries (U.S., Canada, India, and Taiwan). Of the 441 subjects, 122 (28%) completed SB, had  $\geq 50\%$  pain response (i.e.,  $\geq 50\%$  reduction in pain compared to baseline) and were randomized into DB. 122 subjects completed the single-blind phase and were randomized to the double-blind phase. One subject discontinued following randomization without receiving double-blind study medication, so 121 subjects received double-blind study medication and are included in the full analysis set.

The primary endpoint, defined as the time to loss of therapeutic pain response during DB (LTR;  $< 30\%$  pain response relative to the SB baseline mean pain or withdrawal due to lack of efficacy or adverse events), occurred in 34 of 63 (54.0%) patients in the pregabalin group as compared with 41 of 58 (70.7%) subjects in the placebo group. The median time from randomization to LTR was 58 days in the pregabalin group and 22 days in the placebo group. The difference between the treatments was statistically significant (log-rank p-value=0.021).

Pregabalin CR was well tolerated and the safety profile was consistent with the known profile for pregabalin (immediate release) in fibromyalgia patients. Adverse events reported in 5 percent or more of subjects included dizziness, somnolence, peripheral edema, insomnia, headache, fatigue, nausea, weight increased, vision blurred, dry mouth, and disturbance in attention.

## 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](http://www.lyrica.com).

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**DISCLOSURE NOTICE:** The information contained in this release is as of November 19, 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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