# Top-Line Data Show Lyrica Met Primary Endpoint in Clinical Trial as Adjunctive Therapy versus Levetiracetam in Patients with Partial Onset Seizures

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced top-line results for a Phase 3 study that showed Lyrica® (pregabalin) Capsules CV were as effective as levetiracetam as an adjunctive therapy in adult epilepsy patients experiencing refractory partial onset seizures.

The top-line results indicate that the study met its primary endpoint by demonstrating that a comparable proportion of patients on Lyrica achieved at least a 50 percent reduction in the 28-day seizure rate during the maintenance phase relative to levetiracetam. The adverse event profile in the study was consistent with that known for Lyrica.

Epilepsy is a chronic disorder in which seizures occur intermittently. Partial onset seizures (simple, complex, and secondarily generalized tonic-clonic) are the most common, particularly in adults, and often require more than one antiepileptic medication. Patients with refractory partial onset seizures are those patients whose seizures are not completely controlled by medical treatment.

About the Study

The study was a randomized, double-blind, parallel-group, multicenter, comparative, flexible-dose study to compare Lyrica (300, 450, 600 mg/day) to levetiracetam (1,000,

2,000, 3,000 mg/day) in reducing partial onset seizure frequency in subjects with epilepsy.

Subjects included in the study were diagnosed with epilepsy with partial onset seizures for at least two years, and were unresponsive to treatment with at least two but no more than five prior antiepileptic drugs (AEDs) and, at the time of the study enrollment, were on stable dosages of one or two standard AEDs.

The primary efficacy endpoint was the responder rate, defined as the proportion of subjects who had at least a 50 percent reduction in the 28 day seizure rate (all partial seizures) during the 12-week maintenance phase, as measured from the 6-week baseline.

The most common adverse events reported in Lyrica-treated patients were headache, dizziness, insomnia, somnolence, nausea and fatigue. The most common adverse events reported for levetiracetam treated patients were somnolence, dizziness and headache.

Results from this study will be submitted for presentation at upcoming scientific congresses and for publication in a peer-reviewed medical journal.

About Lyrica

Lyrica is currently approved for various indications in 120 countries and regions globally.

In the U.S., Lyrica has been approved by the Food and Drug Administration for five indications. Lyrica was initially approved for partial onset seizures in adults with epilepsy who take one or more drugs for seizures. In 2007, Lyrica became the first FDA-approved treatment for the management of fibromyalgia. Other indications include neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia (pain after shingles) and the management of neuropathic pain associated with spinal cord injury (for which Lyrica became the first FDA- approved treatment in 2012). Lyrica's ongoing clinical development program is focused on the significant unmet needs of patients with certain chronic pain conditions.

In the European Union, Lyrica is approved for four indications: peripheral and central neuropathic pain, generalized anxiety disorder in adults, and partial seizures with or without secondary generalization in adults with epilepsy.

In Japan, Lyrica is the only treatment approved for all three of the following indications: post-herpetic neuralgia, neuropathic pain and pain associated with fibromyalgia.

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 visit www.lyrica.com, in the European Union visit www.ema.europa.eu/ema and in Japan visit www.pfizer.co.jp.

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