Pfizer Reports Top-Line Results of EU Post-Authorization Safety and Efficacy Study of Lyrica's Discontinuation Effects In Patients with Generalized Anxiety Disorder

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that top-line results for Lyrica® (pregabalin) capsules Study A0081147 – Long Term Safety and Efficacy of Pregabalin in Subjects with Generalized Anxiety Disorder (GAD) – demonstrate that drug discontinuation symptoms were low after tapering Lyrica treatment following three months and six months in GAD patients.

The European Medicines Agency (EMA) requested this study to investigate the relationship between dose and duration of treatment on discontinuation symptoms, including rebound anxiety, following long-term treatment with Lyrica in GAD patients. Pfizer will continue to further analyze these top-line results.

Lyrica is approved for the treatment of GAD in adults in the European Union and several other regions around the world, but not in the United States.

GAD is a chronic, debilitating illness characterized by excessive anxiety and worry for at least six months in duration. Often lasting longer than five years, GAD symptoms are both psychological (anxious mood, heightened fears, feelings of tension, difficulty concentrating) and physical (fatigue, pain, feelings of weakness, gastrointestinal disturbance, palpitations, sleep disturbance and restlessness).

About the Study

The objective of the double-blind, placebo- and active-controlled study was to characterize the safety and efficacy of Lyrica lower dosage (150 mg/day – 300 mg/day) and higher dosage (450 mg/day – 600 mg/day) and lorazepam (4 mg/day) compared to placebo following three months and six months of treatment. A total of 621 patients, 615 of whom received at least one dose of study drug, were randomized and treated at 60 centers in 16 countries.

The primary endpoints of the study were met. Efficacy endpoints were the Hamilton Anxiety Rating Scale (HAM-A) total score and Clinical Global Impressions – Severity and Improvement scale (CGI-S). Safety endpoints included adverse events, Physicians Withdrawal Checklist (PWC) – a checklist that rates common symptoms of benzodiazepine withdrawal and common symptoms reported by patients with GAD, Rebound Anxiety (defined as rapid return of the patient's original HAM-A symptoms following drug discontinuation that are worse compared to baseline) and Discontinuation-Emergent Signs and Symptoms (DESS) associated with drug discontinuation (defined as spontaneously reported treatment emergent adverse events that either newly developed during the taper or 1 week follow-up periods, or existed prior to but worsened during the tapering or 1 week follow-up periods). Changes from baseline in HAM-A and PWC were analyzed to assess efficacy and safety including discontinuation symptoms. In order to reflect patients in a real world practice setting, the active comparator, lorazepam, and Lyrica both were tapered prior to discontinuation.

The results confirm that in a large, prospective placebo controlled study, discontinuation of Lyrica was well tolerated compared with placebo. Results demonstrated efficacy was maintained after three months, with a slight continued improvement in patients up to six months of treatment; these are generally consistent with those demonstrated in the Phase 3 registration trials.

In this discontinuation study, the most common adverse events reported in Lyrica-treated patients were headache, dizziness, insomnia, somnolence, nausea, and fatigue. The adverse event profile is consistent with that known for Lyrica.

About Lyrica

Lyrica® is currently approved for various indications in 120 countries and regions globally. In the United States, Lyrica (pregabalin) capsules CV are indicated for 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. In the European Union, Lyrica (pregabalin) is indicated for peripheral and central neuropathic pain, Generalized Anxiety Disorder in adults, and partial seizures with or without secondary generalization in adults with epilepsy. 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 . For Lyrica prescribing information in the European Union, please visit www.ema.europa.eu/ema.

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