Pfizer Reports Top-Line Results from a Phase 3 Study of LYRICA® (pregabalin) Capsules CV in Adults with Post-Traumatic Peripheral Neuropathic Pain

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Pfizer Inc. (NYSE:PFE) announced today top-line results of a Phase 3 study evaluating the efficacy and safety of LYRICA® (pregabalin) Capsules CV in adults with chronic post-traumatic peripheral neuropathic pain. The study did not meet its primary efficacy endpoint.

The study was conducted as a 15-week, double-blind, placebo-controlled, parallel group study with a primary objective to evaluate the efficacy of pregabalin in the treatment of chronic post-traumatic peripheral neuropathic pain. The primary efficacy endpoint was mean pain reduction from baseline compared with placebo based on pain scores from patients' daily pain diaries. The safety profile observed in this study was consistent with that known for pregabalin. The most common adverse events with pregabalin in this study were dizziness, somnolence, nausea and fatigue.

There is currently no treatment approved by the U.S. Food and Drug Administration for post-traumatic neuropathic pain.

Complete study results will be shared on clinicaltrials.gov.

About LYRICA®

LYRICA® is currently approved for various indications in more than 130 countries and regions globally.

LYRICA is 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.

Please click here for the full prescribing information and Medication Guide for LYRICA.

Important Safety Information

LYRICA is not for everyone. LYRICA may cause serious, even life threatening, allergic reactions. Patient should stop taking LYRICA and call their doctor right away if they have any signs of a serious allergic reaction. Some signs are swelling of face, mouth, lips, gums, tongue, throat or neck, trouble breathing, rash, hives or blisters.

Drugs used to treat seizures increase the risk of suicidal thoughts or behavior. LYRICA may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Patients, family members or caregivers should call the doctor right away if they notice suicidal thoughts or actions, thoughts of self harm, or any unusual changes in mood or behavior. These changes may include new or worsening depression, anxiety, restlessness, trouble sleeping, panic attacks, anger, irritability, agitation, aggression, dangerous impulses or violence, or extreme increases in activity or talking. If patients have suicidal thoughts or actions, they should not stop LYRICA without first talking to their doctor.

LYRICA may cause swelling of hands, legs and feet, which can be serious for people with heart problems. LYRICA may cause dizziness and sleepiness. Patients should not drive or work with machines until they know how LYRICA affects them. Patients should tell their doctor right away about muscle pain or problems along with feeling sick and feverish, or any changes in eyesight including blurry vision or if they have any kidney problems or get dialysis.

Some of the most common side effects of LYRICA are dizziness, blurry vision, weight gain, sleepiness, trouble concentrating, swelling of hands and feet, dry mouth, and feeling “high”. Patients with diabetes should tell their doctor about any skin sores.

Patients may have a higher chance for swelling and hives if they are also taking angiotensin converting enzyme (ACE) inhibitors and should tell their doctor if they are taking these medications. Patients may have a higher chance of swelling of hands or feet or gaining weight if they are also taking certain diabetes medicines. Patients should not drink alcohol while on LYRICA. They may have a higher chance for dizziness and sleepiness if they take LYRICA with alcohol, narcotic pain medicines, or medicines for anxiety.

Before starting LYRICA, patients should tell their doctor if they are planning to father a child, or are pregnant, plan to become pregnant, or are breast-feeding. If patients have had a drug or alcohol problem, they may be more likely to misuse LYRICA.

In studies, a specific type of blood vessel tumor was seen in mice, but not in rats. The meaning of these findings in humans is not known.

Patients should not stop taking LYRICA without talking to their doctor. If they stop suddenly they may have headaches, nausea, diarrhea, trouble sleeping, increased sweating, or may feel anxious. Patients with epilepsy may have seizures more often.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

Media:Steve Danehy, 212-733-1538Steven.Danehy@pfizer.comorInvestors:Ryan Crowe, 212-733-8160Ryan.Crowe@pfizer.com