Pfizer Announces Top-Line Results from Phase 3 Trial of LYRICA® (pregabalin) in Primary Generalized Tonic-Clonic Seizures

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NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that a Phase 3 study to assess the use of LYRICA® (pregabalin) as adjunctive therapy for epilepsy patients 5 to 65 years of age with primary generalized tonic-clonic (PGTC) seizures did not meet its primary endpoint. Treatment with LYRICA did not result in a statistically significant reduction in seizure frequency versus placebo. Lyrica is not indicated in any population for the treatment of PGTC seizures. The study was a post-marketing commitment to the U.S. Food and Drug Administration (FDA).

“Pfizer is committed to the study of patient populations with unmet treatment needs, including pediatric and adult patients experiencing generalized tonic-clonic seizures,” said Juan Ovalle, M.D., Global Chief Medical Officer, R&D and Medical, Upjohn, a division of Pfizer. “These data contribute to our growing understanding of pediatric epilepsy and reflect our responsibility to advance scientific knowledge through post-marketing research.”

The LYRICA Pediatric Epilepsy Program is composed of six studies in patients with epilepsy evaluating LYRICA as adjunctive therapy, five of which have been completed. For more information, visit www.clinicaltrials.gov.

About the Study

This Phase 3 study was a 12-week randomized, double-blind, placebo-controlled, multi-center study evaluating the efficacy of two doses of LYRICA in patients 5 to 65 years of

age with PGTC seizures. The study was conducted at 70 sites in 21 countries with 219 patients. Patients were randomized in a 1:1:1 ratio to receive placebo, or one of two fixed doses of LYRICA twice daily: LYRICA 5 mg/kg/day (7 mg/kg/day for subjects with body weight <30 kg, and 300 mg/day for those 17 years of age and older) or LYRICA 10 mg/kg/day (14 mg/kg/day for subjects with body weight <30 kg, and 600 mg/day for those 17 years of age and older).

The safety profile observed in this study was comparable to the known profile of LYRICA in prior epilepsy studies in pediatric and adult patients. The most common adverse events observed with LYRICA were dizziness, headache and somnolence.

About Epilepsy

Epilepsy is a chronic disorder characterized by recurrent, unprovoked seizures and occurs in both adults and children. Sixty-five million people worldwide have epilepsy. In the U.S., more than three million people, including 470,000 children are living with epilepsy. Epilepsy is associated with increased morbidity and mortality and can profoundly affect multiple daily life activities. Primary generalized tonic-clonic seizures, formerly referred to as grand mal seizures, are the most common type of generalized seizures and involve loss of consciousness.

About LYRICA

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

In the U.S., LYRICA is indicated to treat fibromyalgia, diabetic nerve pain, spinal cord injury nerve pain and pain after shingles in adults.

In the U.S., LYRICA is approved as adjunctive therapy for the treatment of partial onset seizures in patients four years of age and older. LYRICA is also indicated to treat partial onset seizures in patients 4 years of age and older with epilepsy who take 1 or more other drugs for seizures.

Please click here for the full prescribing information and Medication Guide for LYRICA or visit http://www.lyrica.com/.

Important Safety Information

LYRICA is not for everyone. LYRICA may cause serious, even life threatening, allergic reactions. Stop taking LYRICA and call your doctor right away if you have any signs of a

serious allergic reaction. Some signs are swelling of your face, mouth, lips, gums, tongue, throat or neck or if you have any trouble breathing, or have a 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 you have suicidal thoughts or actions, do not stop LYRICA without first talking to your doctor.

LYRICA may cause swelling of your hands, legs and feet, which can be serious for people with heart problems. LYRICA may cause dizziness and sleepiness. You should not drive or work with machines until you know how LYRICA affects you. Also, tell your doctor right away about muscle pain or problems along with feeling sick and feverish, or any changes in your eyesight including blurry vision or if you 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 your hands and feet, dry mouth, and feeling “high.” If you have diabetes, tell your doctor about any skin sores.

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

Before you start LYRICA, tell your doctor if you are planning to father a child, or if you are pregnant, or plan to become pregnant. Breastfeeding is not recommended while taking LYRICA. If you have had a drug or alcohol problem, you 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.

Do not stop taking LYRICA without talking to your doctor. If you stop suddenly you may have headaches, nausea, diarrhea, trouble sleeping, increased sweating, or you may feel anxious. If you have epilepsy, you may have seizures more often.

Pfizer Inc.: Working together for a healthier world®

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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of May 24, 2019. 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 LYRICA (pregabalin), including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of LYRICA; 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, 2018 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results,” as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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