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Pfizer Reports Top-line Results From Postherpetic Neuralgia And Painful Diabetic Peripheral Neuropathy Lyrica® Studies Conducted In China

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Pfizer Inc. (NYSE: PFE) announced today top-line results from two placebo-controlled studies conducted in China with Lyrica® (pregabalin) in patients with postherpetic neuralgia (pain after shingles or PHN) and painful diabetic peripheral neuropathy (pDPN), respectively. The PHN Phase 4 study, A0081276, met its primary endpoint by demonstrating a statistically significant reduction in pain when compared to placebo. Separately, the pDPN Phase 3 study, A0081265, did not meet its primary endpoint, a statistically significant change in endpoint mean pain score relative to placebo.

The PHN study was an eight-week, randomized, double-blind, multi-center, placebo-controlled, post-marketing study evaluating the efficacy, safety and tolerability of pregabalin 300mg/day in the treatment of subjects with PHN. For the primary efficacy parameter, change from baseline in weekly mean pain scores (0-10 numeric rating scale), a significant treatment difference of -0.71 points for pregabalin relative to placebo was observed (p=0.0002). The safety profile in this study was consistent with the known profile for Lyrica. The most common adverse events reported for subjects given Lyrica were dizziness, oedema peripheral, dry mouth and somnolence.

PHN, is a type of peripheral neuropathic pain caused by nerve damage. PHN symptoms include continued burning or electric shock-like pain.[1]

The pDPN study was a 11-week randomized, double-blind, multi-center, placebo-controlled study evaluating the efficacy, safety and tolerability of pregabalin 300 mg/day in the treatment of subjects with pDPN. For the primary efficacy parameter, endpoint mean pain score (0-10 numeric rating scale), a treatment difference of -0.28 points for pregabalin relative to placebo was observed (p=0.0559). The safety profile of pregabalin in this study was consistent with the known profile for Lyrica. The most common adverse events reported by subjects given Lyrica were dizziness and somnolence.

pDPN is a form of permanent nerve damage characterized by burning, shooting, pins-and-needles pain in the feet and hands[2].

Full results for both studies will be submitted for publication when analyses are complete.

About Lyrica

Lyrica® is currently approved for various indications in 120 countries and regions globally. In China, where these two studies were conducted, Lyrica is approved for PHN.

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.

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 FM.

Lyrica's ongoing clinical development program is focused on the significant unmet needs of patients with certain chronic pain conditions.

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

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, plan to become pregnant, or are breast-feeding. 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.

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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.

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[1] UCSF Medical Center. Post-Herpetic Neuralgia. Last accessed at http://www.ucsfhealth.org/conditions/post-herpetic_neuralgia/. on 25 July 2014.

[2] Peri, C. (2012). The pain of diabetes: peripheral neuropathy. Last accessed at http://diabetes.webmd.com/peripheral-neuropathy-8/nerve-pain-overview on 25 July 2014.

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