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Pfizer Reports Top-Line Results From A Phase 4 Study Evaluating LYRICA® Capsules CV As A Treatment For Adolescents With Fibromyalgia

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Pfizer Inc. (NYSE:PFE) announced today top-line results of a double-blind Phase 4 study evaluating the safety and efficacy of Lyrica® (pregabalin) Capsules CV in adolescents (ages 12-17 years) with fibromyalgia (FM). The primary endpoint of the study was not achieved as there was not a statistically significant difference between pregabalin and placebo in mean pain score. The treatment difference was 0.66 points, which reflects an improvement of 1.60 points from baseline for pregabalin-treated patients and 0.94 points for placebo (p=0.121). This study was conducted to fulfill a post-marketing commitment required by the U.S. Food and Drug Administration (FDA) when Lyrica was approved for the management of fibromyalgia. The safety and efficacy of pregabalin in pediatric patients have not been established.

A total of 107 adolescent patients were enrolled in this Phase 4, 15-week double-blind, randomized, placebo-controlled study from multiple centers across the U.S., Europe and Asia. This study is the first large pharmacological treatment study to be completed in this study population.

"Pfizer is committed to better understanding the full clinical profile of our approved medicines in pediatric and adolescent patients. This study advances the understanding of this patient population," said Steve Romano, MD, senior vice president and Head, Global Medicines Development for the Pfizer Global Innovative Pharmaceutical business. "Lyrica has more than 10 years of real world experience supporting the needs of patients and remains an important treatment choice for healthcare professionals. These results do not change the established benefit of Lyrica for its approved indications, including fibromyalgia in adults."

Study medication was administered twice daily. Dosing started at 75 mg/day and was optimized over a 3 week period, based on tolerability and response, to a dose of 75 mg/day, 150 mg/day, 300 mg/day or 450 mg/day, with the optimized dose maintained for the next 12 weeks.

The safety profile observed in this study is consistent with the known profile for Lyrica in prior fibromyalgia studies in adults, with the exception of mild nausea, which occurred at a higher rate in pregabalin-treated patients. The most common adverse events in this study in pregabalin treated patients were dizziness, nausea, headache, increased weight and fatigue.

Full results from the study are expected to be submitted for publication when analyses are complete.

About Lyrica

Lyrica® is currently approved for various indications in 139 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.

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.

Important Safety Information

LYRICA is contraindicated in patients with known hypersensitivity to pregabalin or any of its other components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.

There have been postmarketing reports of hypersensitivity in patients shortly after initiation of treatment with LYRICA. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. Discontinue LYRICA immediately in patients with these symptoms.

There have been postmarketing reports of angioedema in patients during initial and chronic treatment with LYRICA. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. Discontinue LYRICA immediately in patients with these symptoms.

Antiepileptic drugs (AEDs) including LYRICA increase the risk of suicidal thoughts or behavior in patients taking AEDs for any indication. Monitor patients treated with any AED for any indication for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Pooled analyses showed clinical trial patients taking an AED had approximately twice the risk of suicidal thoughts or behavior than placebo treated patients. The estimated incidence rate of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one patient for every 530 patients treated with an AED.

The most common adverse reactions across all LYRICA clinical trials are dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, constipation, euphoric mood, balance disorder, increased appetite, and thinking abnormal (primarily difficulty with concentration/attention).

Inform patients taking LYRICA that dizziness and somnolence may impair their ability to perform potentially hazardous tasks such as driving or operating complex machinery until they have sufficient experience with LYRICA to determine its effect on cognitive and motor function.

In controlled studies, a higher proportion of patients treated with LYRICA reported blurred vision (7%) than did patients treated with placebo (2%), which resolved in a majority of cases with continued dosing. Consider more frequent assessment for patients who are already routinely monitored for ocular conditions.

Higher frequency of weight gain and edema was observed in patients taking both LYRICA and thiazolidinedione antidiabetic drugs. Exercise caution when coadministering these drugs. Patients who are taking other drugs associated with angioedema such as angiotensin converting enzyme inhibitors (ACE- inhibitors) may be at increased risk of developing angioedema. Exercise caution when using LYRICA in patients who have had a previous episode of angioedema.

LYRICA may exacerbate the effects of oxycodone, lorazepam, or ethanol on cognitive and gross motor functioning.

Patients with a history of drug or alcohol abuse may have a higher chance of misuse or abuse of LYRICA.

Withdraw LYRICA gradually over a minimum of 1 week. Discontinue LYRICA immediately in patients with symptoms of hypersensitivity or angioedema.

Patients with a creatinine clearance of 30 to 60 mL/min had a greater incidence of discontinuation due to adverse reactions than patients with normal creatinine clearance. Adjust the daily dose of LYRICA for patients with reduced renal function (creatinine clearance ?60 mL/min) and in those undergoing hemodialysis. Administer a supplemental dose of LYRICA immediately following every 4-hour hemodialysis treatment.

In standard, preclinical in vivo lifetime carcinogenicity studies of LYRICA, an unexpectedly high incidence of hemangiosarcoma was identified in 2 different strains of mice. The clinical significance of this finding is unknown. In clinical studies across various patient populations comprising 6396 patient-years of exposure in patients >12 years of age, new or worsening preexisting tumors were reported in 57 patients.

Please see full LYRICA prescribing information at www.LYRICA.com.

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, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

Pfizer Inc. Media: Steven Danehy, 212-733-1538 or Investors Ryan Crowe, 212-733-8160