Pfizer Logo

Pfizer Reports Positive Results From Phase 3 Trial Of Lyrica (pregabaline) Capsules CV In Restless Legs Syndrome

Thursday, December 15, 2011 - 04:30pm

Top-Line Results Show Lyrica Met All Co-Primary Endpoints

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that a Phase 3 study for Lyrica (pregabalin) in patients with Restless Legs Syndrome (RLS) met each of its three co-primary endpoints, showing significant benefit as compared with placebo and pramipexole. Pfizer will continue to further analyze these top-line results.

The study, A0081186, was a randomized, double-blind, 12-month trial. It enrolled more than 700 patients, who received either a placebo, Lyrica at 300 mg/day, pramipexole at 0.25 mg/day or pramipexole at 0.5 mg/day.

Patients treated with Lyrica experienced a statistically significant improvement compared with placebo in RLS symptom severity as measured by the International Restless Leg Group Rating Scale following 12 weeks of treatment. The Lyrica group also demonstrated a statistically significant improvement following 12 weeks of treatment in the proportion of patients responding to treatment compared with those on placebo as measured by the Clinical Global Impression Improvement scale. In addition, Lyrica treatment resulted in a statistically significant reduction in the rate of augmentation (worsening of RLS symptoms that occur after starting a medication to treat RLS) compared with pramipexole 0.5 mg/day over 12 months.

The results for this study indicate that the most common adverse events in Lyrica-treated patients were dizziness, somnolence, fatigue, headache and nasopharyngitis (inflammation of the nasal cavity and throat). The adverse event profile is consistent with that known for pregabalin.

Restless Legs Syndrome is a neurological condition that is characterized by an unpleasant irresistible urge to move the legs and, in severe cases, other parts of the body. The symptoms have a circadian pattern and occur mostly in the evening and bedtime. It often results in difficulty falling or staying asleep and can result in periodic limb movements while sleeping, causing partial awakenings that disrupt sleep. RLS has profound negative impact on patients' quality of life.

Top-line results from a previous Phase 3 study in RLS patients, A0081185, showed Lyrica demonstrated statistically significant improvements in the primary endpoint, sleep maintenance, compared with placebo in adults with RLS.

The preliminary results of the previous study indicate that the most common adverse events in Lyrica-treated patients were dizziness, somnolence, headache, nausea, dry mouth, upper respiratory tract infection and disturbance of attention. The adverse event profile is consistent with that known for pregabalin.

At present, Pfizer does not have plans to seek regulatory approval for an indication in Restless Legs Syndrome.

About Lyrica

Lyrica® is currently approved in 110 countries and regions globally. In the United States, Lyrica (pregabalin) capsules CV is approved to treat Diabetic Nerve Pain, Pain after Shingles, Fibromyalgia and partial onset seizures in adults with epilepsy who take one or more drugs for seizures. Lyrica is not approved to treat Restless Legs Syndrome in any country. Treatment with Lyrica may cause dizziness, somnolence, peripheral edema or blurred vision. Other most common adverse reactions include dry mouth, weight gain, constipation, euphoric mood, balance disorder, increased appetite and thinking abnormally. There have been post-marketing reports of angioedema and hypersensitivity. Like other anti-epileptic drugs, Lyrica may cause suicidal thoughts or actions in a very small number of people.

For Lyrica prescribing information, please visit www.lyrica.com.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also 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 about our commitments, please visit us at www.pfizer.com.

Pfizer Inc. Media: MacKay Jimeson, 212-733-2324 or Investors: Suzanne Harnett, 212-733-8009