Lyrica Significantly Reduced Pain and Improved Other Symptoms of Post-Traumatic Peripheral Nerve Pain, New Data Show

Wednesday, April 29, 2009 - 06:00am

(BUSINESS WIRE)--Patients suffering from post-traumatic peripheral nerve pain treated with Lyrica® (pregabalin) capsules CV experienced significantly reduced pain compared to those taking placebo, according to new data presented today at the American Academy of Neurology annual meeting. The data also showed that patients treated with Lyrica reported less pain interference with sleep and were significantly more likely to report feeling better overall at the end of the study compared with placebo.

Post-traumatic peripheral nerve pain is a difficult to treat condition that occurs after nerve damage due to trauma from accidental injury or surgery. It can be a chronic condition, affecting the injured area with pain persisting long after the initial injury has healed. Traumatic injury causing long-lasting changes to the peripheral nervous system – the communications network that transmits information to and from the central nervous system (the brain and spinal cord) and every other part of the body – is believed to be the cause of this persistent pain. Post-traumatic peripheral nerve pain can have a wide array of symptoms, including numbness, tingling and prickling sensations, sensitivity to touch or more extreme symptoms including burning pain.

“The findings of the study are good news for the many patients who suffer from this painful and debilitating condition,” said Robert van Seventer, MD, Chair of the Department of Anesthesiology and Director of Amphia Pain Clinic and Research Centre, Amphia Hospital, the Netherlands. “Post-traumatic peripheral neuropathic pain has historically been a challenging condition to treat so this data demonstrating the ability of pregabalin to provide relief for patients is encouraging.”

The study found patients treated with Lyrica experienced significantly reduced pain compared to those taking placebo. At the end of the study, patients receiving Lyrica had, on average, a pain score that was 0.62 points lower on an 11-point scale compared to placebo. Patients receiving Lyrica reported less pain interference with sleep compared to placebo. At the end of the study, patients receiving Lyrica had an average self-reported weekly pain-related sleep interference score of 2.73 (from a baseline of 4.1) on an 11-point scale measuring how much pain had interfered with sleep during the past 24 hours, compared to 4.13 for placebo (from a baseline of 4.8). Additionally, at the end of the study, significantly more patients receiving Lyrica (64 percent) reported feeling “improved” compared to placebo (41 percent).

About the Study

The multi-center, double-blind, placebo controlled study of Lyrica in 254 adult patients with post-traumatic peripheral neuropathic pain randomized patients to receive flexible dose Lyrica 150 mg to 600 mg daily for four weeks of dose optimization, followed by fixed dosing for four weeks. The study was conducted at 60 sites across Canada and Europe. The average Lyrica dose was 326 mg daily. Patients had to experience persisting, neuropathic pain for at least three months following a traumatic event such as an accident, surgery, amputation or a nerve injury and have a pain score greater than or equal to 4 on an 11-point scale. Patients remained on existing treatments during the study.

Patients were asked to measure their pain on a scale of zero to 10; the average baseline scores for study participants were 6.0 in the pregabalin group and 6.3 in the placebo group on this 11-point scale. A score of 4.0 to 7.0 is considered moderate pain and a score of greater than 7.0 is considered severe pain.

The primary endpoint was the difference in average self-reported pain score at the study’s conclusion between patients treated with Lyrica and placebo. Secondary endpoints included the effects of Lyrica compared to placebo on co-morbid symptoms of post-traumatic peripheral neuropathic pain including anxiety, patients’ self-reported pain-related sleep and patients’ self-reported overall improvements.

The most common side effects in the study versus placebo were dizziness (43.3 percent vs. 9.4%) and somnolence (15.7 percent vs. 6.3%), followed by headache (11.8 percent vs. 11.0%), fatigue (11.8 percent vs. 7.9%) and dry mouth (11.0 percent vs. 4.7%).

The study was funded by Pfizer Inc.

About Lyrica

In the United States, Lyrica is approved for the management of fibromyalgia. Lyrica is also indicated for the management of painful diabetic peripheral neuropathy, postherpetic neuralgia (pain after shingles), and for the adjunctive treatment of partial onset seizures (a type of epilepsy) in adults. Outside of the United States, Lyrica is indicated in adults for the management of peripheral and central neuropathic pain (NeP), treatment of generalized anxiety disorder, and adjunctive therapy for partial seizures with or without secondary generalization.

Important Safety Information

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.

Pfizer Inc: Working together for a healthier world™

Founded in 1849, Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

Pfizer IncMedia:Sally Beatty, 212-733-6566Investor:Jennifer Davis, 212-733-0717