Pfizer's Lyrica® (Pregabalin) Capsules CV Receives Approval for Treatment of Peripheral Neuropathic Pain In Japan

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First Treatment Approved for Common Pain Conditions Filling Important Unmet Need for Patients in Japan

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NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the Japanese Ministry of Health, Labour and Welfare approved Lyrica® (pregabalin) capsules for the treatment of peripheral neuropathic pain. This follows the recent approval in Japan of Lyrica for the treatment of postherpetic neuralgia on April 16, 2010. Lyrica is the first medication approved for peripheral neuropathic pain in Japan where it is co-promoted with Eisai Co., Ltd.

"Neuropathic pain remains an under-diagnosed condition in many parts of the world, in large part due to low awareness and understanding of the condition and the fact that there are few proven treatment options available," said Steve Romano, M.D., vice president, Medical Affairs Head, Primary Care Business Unit at Pfizer. "This approval reinforces the benefit that Lyrica can bring to appropriate patients suffering from peripheral neuropathic pain."

Peripheral neuropathic pain, or peripheral nerve pain, is a difficult-to-treat chronic pain condition. It is initiated or caused by a primary lesion or dysfunction in the peripheral nervous system. The pain symptoms that patients experience are often described as burning, tingling or shock-like sensations. Peripheral neuropathic pain may be triggered

by a variety of medical conditions including nerve injury, sciatica, fibromyalgia, diabetes, infection (herpes zoster), cancer, HIV infection and HIV treatment. Research has shown that patients with neuropathic pain are often prescribed medications that have no demonstrated efficacy in treating this type of pain or have significant side effects.

The Lyrica approval was based on ten Phase 3 double-blind studies including eight Western studies and two studies in Japan. The first study in Japan was previously reviewed by the Japanese regulatory authorities in support of the postherpetic neuralgia indication in April 2010. The second study in Japan was conducted to support the peripheral neuropathic pain indication and was a comparative study of Lyrica and placebo in Japanese patients with diabetic peripheral neuropathy. Results showed that Lyrica reduced symptoms of peripheral neuropathic pain as early as week one of treatment for some patients and maintained those improvements for the duration of the 13-week study. Although the exact mechanism of Lyrica is unknown, it is believed to calm neurons that cause neurologic pain.

This Phase 3 double-blind diabetic peripheral neuropathic study conducted in Japan included a total of 314 patients: 135 on placebo, 134 on Lyrica 300mg per day and 45 on Lyrica 600mg per day. Both Lyrica treatments reduced pain scores during the comparative study from baseline: -1.94 for Lyrica 600mg, -1.82 for Lyrica 300mg and -1.20 for placebo based on an 11-point numeric rating scale.

The most common adverse events in the Japanese peripheral neuropathic study were somnolence (24.5%), dizziness (22.5%), and edema (17.2%).

About Lyrica

Lyrica® is currently approved in 110 countries and regions globally. In the United States, Lyrica (pregabalin) capsules CV is approved by the U.S. Food and Drug Administration (FDA) for the management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, fibromyalgia and as adjunctive therapy for adult patients with partial onset seizures.

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

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