Pfizer’s Lyrica Top-Line Results Positive In Global Phase 3 Study Of Central Neuropathic Pain Following Spinal Cord Injury

Monday, June 20, 2011 - 10:00pm

"We are pleased with the top-line results of this study and look forward to more fully understanding the benefit that Lyrica may bring to these patients,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that top-line results for Lyrica Study A0081107 – Central Neuropathic Pain Following Spinal Cord Injury – demonstrated that the study met its primary endpoint: positive efficacy in reducing Central Neuropathic Pain following Spinal Cord Injury with Lyrica (pregabalin) compared to placebo. Further analysis will be conducted on these initial results.

Central Neuropathic Pain is a heterogeneous group of pain conditions initiated or caused by a primary lesion in the central nervous system and occurs often following spinal cord injury.

“We are pleased with the top-line results of this study and look forward to more fully understanding the benefit that Lyrica may bring to these patients,” said Steven J. Romano, M.D., senior vice president, Head, Medicines Development Group, Global Primary Care Business Unit, Pfizer, Inc.

Study A0081107 was a randomized, double-blind, placebo-controlled, parallel group, multi-center study comparing pregabalin flexibly dosed (150-600mg/day, dosed twice-daily) and placebo in subjects with chronic Central Neuropathic Pain following traumatic spinal cord injury. A total of 220 subjects were enrolled in the study (112 pregabalin and 108 placebo) in 66 investigative sites in 10 countries. The primary endpoint was the duration adjusted average change (DAAC), which is a weighted average of change in pain

scores based on the duration a subject participated in the study. The preliminary results of the study indicate that the most common adverse events in Lyrica-treated patients were somnolence, dizziness, edema, fatigue, dry mouth, insomnia and blurred vision.

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 Central Neuropathic Pain in the U.S. 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.

DISCLOSURE NOTICE: The information contained in this release is as of June 21, 2011. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties regarding a potential additional indication for Lyrica, including its potential benefits. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any supplemental drug applications that may be filed for such indication as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential, as well as competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.

Pfizer Inc. Media: MacKay Jimeson, 212-733-2324 or Investors: Jennifer Davis, 212-733-0717