Positive Top-Line Results For Pfizer’s Lyrica In Phase 3 Study Of Patients With Fibromyalgia In Japan

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(BUSINESS WIRE)--Pfizer Japan announced today the top-line results for Lyrica (pregabalin) Study A0081208 – Randomized, Double-Blind, Multicenter, Placebo-Controlled Study to Evaluate Efficacy and Safety of Pregabalin (CI-1008) in the Treatment of Fibromyalgia. The results demonstrated a statistically significant reduction in the endpoint mean pain score, the primary efficacy analysis in the study, with pregabalin compared to placebo. Further analyses will be conducted on these initial results.

The essential features of fibromyalgia are chronic widespread musculoskeletal pain and tenderness. The pathophysiology of fibromyalgia is complex and not well understood, but fibromyalgia is a disabling disorder that adversely affects quality of life in these afflicted patients.

“We are pleased with the top-line results of this study and look forward to more fully understanding the potential benefits that Lyrica may bring to fibromyalgia patients in Japan,” said Akihisa Harada, M.D., vice president, Head of Development Japan, at Pfizer Japan.

Study A0081208 was a 16-week, randomized, double-blind, placebo-controlled, parallel group, multi-center study comparing pregabalin flexibly dosed (300-450mg/day, dosed twice-daily) and placebo in subjects with fibromyalgia. A total of 501 subjects were

enrolled in the study (251 pregabalin and 250 placebo) in 45 investigative sites in Japan. The preliminary results of the study indicate that the most common adverse events in the study were somnolence, dizziness, weight increased, constipation, feeling abnormal, edema peripheral and blurred vision.

About Lyrica

Lyrica® is currently approved in 110 countries and regions globally. In Japan, Lyrica (pregabalin) capsules CV is approved to treat peripheral neuropathic pain. Lyrica is not approved to treat fibromyalgia in Japan.

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.

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This release contains forward-looking information that involves substantial risks and uncertainties regarding a potential additional indication for Lyrica in Japan, 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.

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