Pfizer Logo

Pfizer Reports Top-Line Results of Study of Lyrica's Effect on Male Reproduction Conducted as a Post-Approval Commitment Required by the U.S. Food and Drug Administration

Sunday, July 22, 2012 - 09:30pm

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that top-line results for Lyrica® (pregabalin) capsules CV Study A0081104 – Assessment of the Impact of Lyrica on Sperm Production in Healthy Volunteers – demonstrate that Lyrica does not affect the reproductive function in healthy males when compared to placebo.[1] The study was conducted as a post-approval commitment required by the US Food and Drug Administration (FDA).[1] Pfizer will continue to further analyze the study results.

About the Study

The objective of the Phase 4, multicenter, double-blind, randomized, placebo-controlled study was to evaluate the effects of Lyrica as compared to placebo on sperm concentration in healthy males.[1] A total of 222 subjects were randomized at 12 study centers in the United States.[1] One hundred and eleven subjects received Lyrica and 109 subjects received placebo for 12 weeks followed by a 3-month washout period.[1] Subjects in the Lyrica arm received 600 mg/day (300 mg twice daily) for 10 weeks after a 2-week titration that started at 100 mg/day (50 mg BID).[1] Subjects who could not tolerate 600 mg/day had their dosage reduced to 450 mg/day (225 mg BID) and those who were unable to tolerate 450 mg/day were dropped from the study.[1]

The primary endpoint of the study, the proportion of subjects with a 50 percent or more reduction in sperm concentration from baseline to end of study (week 26) last observation, was met.[1]

The most common adverse events in subjects who received Lyrica compared to those who received placebo were dizziness, somnolence, dissociation and fatigue.[1] The adverse event profile is consistent with that known for Lyrica.[1]

About Lyrica

Lyrica is currently approved for various indications in 120 countries and regions globally. In the United States, Lyrica is indicated for diabetic nerve pain, post herpetic neuralgia (pain after shingles), fibromyalgia, neuropathic pain associated with spinal cord injury and partial onset seizures in adults with epilepsy who take one or more drugs for seizures. Antiepileptic drugs (AEDs) including Lyrica increase the risk of suicidal thoughts or behavior in patients taking AEDs for any indication. There have been post-marketing reports of angioedema and hypersensitivity with Lyrica. Treatment with Lyrica may cause dizziness, somnolence, dry mouth, edema and blurred vision. Other most common adverse reactions include weight gain, constipation,

euphoric mood, balance disorder, increased appetite and thinking abnormal (primarily difficulty with concentration/attention.)

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.

[1] Data on File. 1104 Clinical Study Report, Pfizer.

Pfizer Inc. MacKay Jimeson, 212-733-2324 (media) Suzanne Harnett, 212-733-8009 (investors)