# Pfizer Stops Phase 3 Trial Of Lyrica (pregabalin) Capsules CV In Neuropathic Pain Associated With HIV Neuropathy

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that it has stopped a Phase 3 clinical trial of Lyrica (pregabalin) in patients with neuropathic pain associated with HIV neuropathy, a form of nerve damage characterized by burning pain usually beginning in the feet. The decision follows review of a planned interim analysis of the study by the trial’s external Data Monitoring Committee (E-DMC). There were no safety concerns raised in the E-DMC review ofmore...

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The protocol for study A0081244 – A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Trial of Pregabalin Versus Placebo in the Treatment of Neuropathic Pain Associated with HIV Neuropathy - called for an interim efficacy analysis when approximately half of the planned 416 subjects had been enrolled. The interim analysis included a total of 246 subjects randomized, and the results revealed that the improvements in neuropathic pain symptoms in this study were virtually identical

between the Lyrica and placebo treatments.

The primary endpoint of the study was mean pain score derived from subject's diary for daily average pain on an 11-point pain numeric rating scale. The study also assessed a number of secondary safety and efficacy endpoints.

“The results of this study show the complexities of studying pain, particularly in a difficult-to-treat condition such as neuropathic pain associated with HIV neuropathy for which there are no approved medications in the United States,” said Steven J. Romano, M.D., senior vice president, Head, Medicines Development Group, Global Primary Care Business Unit, Pfizer Inc. “The study of Lyrica for this condition is an example of Pfizer’s dedication to better understanding neuropathic pain and to providing data and developing treatments to address areas of patient need.” Lyrica is not approved in the U.S. for the treatment of neuropathic pain associated with HIV neuropathy.

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. 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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