Pfizer’s Lyrica Receives Complete Response Letter From FDA For Generalized Anxiety Disorder Monotherapy Treatment

Wednesday, December 23, 2009 - 08:36am

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the Food and Drug Administration (FDA) issued a Complete Response letter regarding the company’s New Drug Application (NDA) for Lyrica® (pregabalin) capsules CV as a monotherapy treatment for generalized anxiety disorder (GAD). The FDA determined that the data contained in the NDA were insufficient to support approval. The application was a resubmission in response to a “not-approvable” letter issued by the FDA in August 2004. The FDA continues to review a separate application for Lyrica as adjunctive therapy for the treatment of GAD.

“We are disappointed with the FDA’s decision and will work with the agency to determine next steps,” said Steve Romano, vice president, Medical Affairs Head, Primary Care Business Unit. “Given the chronic nature of GAD and the number of patients who continue to experience anxiety symptoms despite treatment, there is a clear unmet need for new and different treatment options.”

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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 December 23, 2009. 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 potential additional indications for Lyrica. Such risks and uncertainties include, among other things, whether and when the U.S. Food and Drug Administration will approve new drug applications for such additional indications and its decisions regarding labeling and other matters that could affect their 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, 2008 and in its reports on Form 10-Q and Form 8-K.

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