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Product News



Merck Announces Voluntary Worldwide Withdrawal of VIOXX®

WHITEHOUSE STATION, N.J., Sept. 30, 2004 - Merck & Co., Inc. today announced a voluntary worldwide withdrawal of VIOXX® (rofecoxib), its arthritis and acute pain medication. The company's decision, which is effective immediately, is based on new, three-year data from a prospective, randomized, placebo-controlled clinical trial, the APPROVe (Adenomatous Polyp Prevention on VIOXX) trial.

The trial, which is being stopped, was designed to evaluate the efficacy of VIOXX 25 mg in preventing recurrence of colorectal polyps in patients with a history of colorectal adenomas. In this study, there was an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, beginning after 18 months of treatment in the patients taking VIOXX compared to those taking placebo. The results for the first 18 months of the APPROVe study did not show any increased risk of confirmed cardiovascular events on VIOXX, and in this respect, are similar to the results of two placebo-controlled studies described in the current U.S. labeling for VIOXX.

"We are taking this action because we believe it best serves the interests of patients," said Raymond V. Gilmartin, chairman, president and chief executive officer of Merck. "Although we believe it would have been possible to continue to market VIOXX with labeling that would incorporate these new data, given the availability of alternative therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take."

APPROVe was a multi-center, randomized, placebo-controlled, double-blind study to determine the effect of 156 weeks (three years) of treatment with VIOXX on the recurrence of neoplastic polyps of the large bowel in patients with a history of colorectal adenoma. The trial enrolled 2,600 patients and compared VIOXX 25 mg to placebo. The trial began enrollment in 2000.

VIOXX was launched in the United States in 1999 and has been marketed in more than 80 countries. In some countries, the product is marketed under the trademark CEOXX. Worldwide sales of VIOXX in 2003 were \$2.5 billion.

Results of the VIGOR (VIOXX Gastrointestinal Outcomes Research) study, released in March 2000, demonstrated that the risk of gastrointestinal toxicity with VIOXX was less than with naproxen, but indicated an increased risk of cardiovascular events versus naproxen. However, in other studies including Merck's Phase III studies that were the basis of regulatory approval of the product, there was not an increased risk of cardiovascular events with VIOXX compared with placebo or VIOXX compared with other non-naproxen non-steroidal anti-inflammatory drugs (NSAIDs). Merck began long-term randomized clinical trials to provide an even more comprehensive picture of the cardiovascular safety profile of VIOXX.

"Merck has always believed that prospective, randomized, controlled clinical trials are the best way to evaluate the safety of medicines. APPROVe is precisely this type of study - and it has provided us with new data on the cardiovascular profile of VIOXX," said Peter S. Kim, Ph.D., president of Merck Research Laboratories. "While the cause of these results is uncertain at this time, they suggest an increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy. While we recognize that VIOXX benefited many patients, we believe this action is appropriate."

Merck has informed the U.S. Food and Drug Administration and regulatory authorities in other countries of its decision. The company also is in the process of notifying health care practitioners in the United States and other countries where VIOXX is marketed. Patients who are currently taking VIOXX should contact their health care providers to discuss discontinuing use of VIOXX and possible alternative treatments. In addition, patients and health care professionals may obtain information from www.merck.com and www.vioxx.com, or may call (888) 36-VIOXX (1-888-368-4699).

The results of clinical studies with one molecule in a given class are not necessarily applicable to others in the class. Therefore, the clinical significance of the APPROVe trial, if any, for the long-term use of other drugs in this class, consisting of COX-2 specific inhibitors and NSAIDs, is unknown. The company will work with regulatory authorities in the 47 countries where ARCOXIA is approved to assess whether changes to the prescribing information for this class of drugs, including ARCOXIA, are warranted. Merck is continuing to seek approval for ARCOXIA in other countries, including the United States.

Merck will continue its extensive clinical program to collect additional longer-term data for ARCOXIA, its medication for arthritis and acute pain.

With regard to financial guidance, prior to today's announcement, Merck remained comfortable with its 2004 earnings per share guidance of \$3.11 to \$3.17. The company currently expects earnings per share to be negatively affected by \$0.50 to \$0.60 as a result of today's announcement. This estimate includes foregone sales, writeoffs of inventory held by Merck, customer returns of product previously sold and costs to undertake the pullback of the product. Included in this cost estimate is the expectation of foregone fourth quarter sales of VIOXX of \$700 million to \$750 million. In addition, Merck expects that worldwide approximately one month of inventory is held by customers and will be returned.

At this point it is uncertain which of these costs will be recorded in the third quarter and which will be recorded in the fourth quarter. Therefore, at this point, Merck is retracting the third quarter guidance it had previously provided.

Merck will report third-quarter earnings on Oct. 21. At that point, the company will provide additional information regarding the costs for product withdrawal.

About Merck

Merck & Co., Inc. is a global research-driven pharmaceutical company. Merck discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health, directly and through its joint ventures.

Forward Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2003, and in its periodic reports on Form 10-Q and Form 8-K (if any), which the company incorporates by reference.

VIOXX® (rofecoxib) is a registered trademark of Merck & Co., Inc.

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