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## Statement

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### **Merck & Co., Inc. Statement About COX-2 Inhibitor Review Studies in the *Journal of the American Medical Association***

WHITEHOUSE STATION, N.J., Sept. 12, 2006 – Merck believes that observations published in today's *Journal of the American Medical Association (JAMA)*, and the opinions expressed in an accompanying editorial, regarding a potential increased short-term cardiovascular thrombotic risk of VIOXX, are not supported by the current weight of the clinical trial data.

The article by McGettigan et al., reviewed prior reported observational data on the cardiovascular risk with COX-2 inhibitors and NSAIDs. Merck values ongoing debate, analysis and evolving medical opinion as part of the scientific process, but notes that observational data on COX-2 inhibitors and NSAIDs have resulted in a range of different findings with a cardiovascular risk observed in some studies but not others. It is widely accepted, as acknowledged by McGettigan et al., that observational studies are associated with inherent limitations, including factors that cannot be adequately controlled for and ability to fully account for differences in risk factors between groups. Merck believes it is not appropriate to draw conclusions from these types of analyses when they contradict findings from randomized, controlled clinical trials, which are the gold standard in evaluating the safety and efficacy of medicines.

Merck believes that previously reported data from randomized, controlled clinical trials with VIOXX do not support the interpretations published today in *JAMA* that there is an increased cardiovascular thrombotic risk with short-term use of VIOXX compared with non-naproxen NSAIDs or placebo.

In the APPROVe study, for the first time, an increased relative risk for confirmed thrombotic cardiovascular events for patients taking VIOXX compared with those taking placebo was observed after 18 months of continuous use.

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Contrary to the views expressed in an accompanying *JAMA* editorial by Graham, Merck properly and thoroughly researched and reported results from VIOXX clinical trials involving almost 10,000 patients prior to approval, and continued to monitor and assess the benefit/risk profile of VIOXX while it was on the market.

The article in the same *JAMA* issue by Zhang et al., addressed the known renovascular risk associated with COX-2 inhibitors and NSAIDs through a meta-analysis of prior clinical trials. It is important to recognize that since VIOXX was first marketed, the product label has included precautionary information about the risk of peripheral edema and hypertension in certain individuals, which are well-documented adverse effects associated with NSAIDs.

### **About Merck**

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs.

The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit [www.merck.com](http://www.merck.com).

### **Forward-Looking Statement**

This statement contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and 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 statement 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, 2005, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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