

**Statement Regarding the Publications of Two VIOXX Studies:  
The ViP Trial in *Current Medical Research and Opinion* and  
The VICTOR Trial in the *New England Journal of Medicine***

WHITEHOUSE STATION, N.J., July 25, 2007 – The cardiovascular (CV) findings from the ViP trial, a randomized, placebo-controlled trial designed to evaluate the effect of VIOXX in decreasing the risk of prostate cancer, were reported this week in the journal *Current Medical Research and Opinion*.

Additionally, the CV findings from the VICTOR trial, a randomized, placebo-controlled trial designed to evaluate the effect of VIOXX in treating patients with colorectal cancer, have recently been published in the *New England Journal of Medicine*.

The ViP trial was stopped early on Sept. 30, 2004, due to the worldwide withdrawal of VIOXX. In early 2005, interim data from this study were provided to the U.S. Food and Drug Administration (FDA) and discussed at the FDA Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. Final results from the ViP trial were posted to [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org) in September 2005.

In the study, the risk of confirmed CV events during treatment with VIOXX and placebo were similar. Twenty-nine patients (14 VIOXX, 15 placebo) experienced confirmed thrombotic CV events in the ViP trial. A total of 4,741 men were enrolled in the study (2,369 randomized to VIOXX 25 mg, and 2,372 to placebo). Baseline demographics were similar in the two treatment groups, and median duration of treatment was 4.14 months (range 0.03 to 15.9 months).

In the ViP study, all of the CV data were collected prior to patient and investigator unblinding. All reported thrombotic CV events occurring on-treatment or within 14 days after study drug discontinuation were adjudicated by an independent panel of clinical experts blinded to treatment assignment. An independent confirmation of the analyses of the ViP study was performed by Warwick Clinical Trials Unit in Warwick, U.K.

The study authors acknowledge that limitations in the ViP study – specifically, the short period of drug exposure, the uncompleted enrollment, and the relatively small number of thrombotic CV events observed – do not allow firm conclusions to be drawn regarding the relative CV safety of VIOXX 25 mg compared to placebo from this study alone.

The purpose of reporting the results from the ViP study is to provide the scientific community with the CV safety data in a peer-reviewed scientific publication in order to add to

the body of published scientific literature regarding this important topic. These data will aid future scientific discussions of the published literature surrounding the CV safety of COX-2 selective and traditional NSAIDs.

In the VICTOR study, which was also terminated early on Sept. 30, 2004, there was an increased relative risk of confirmed CV events during treatment with VIOXX relative to placebo. Results of this study were also limited by premature study termination and a small number of events; in addition, other limitations of the VICTOR study included the reporting of CV events after unblinding, and an imbalance in baseline CV risk factors between the VIOXX and placebo groups.

Limited, preliminary data from the VICTOR study were provided to the U.S. Food and Drug Administration (FDA) and discussed at the FDA Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee in 2005.

The scientists at Oxford University who authored the paper acknowledge several limitations of the study, including the small number of confirmed CV events available for analysis and the fact that some events were reported only after patients and investigators had been unblinded to study treatment, a potential source of bias. Also, patients who were randomized to VIOXX had more pre-existing CV risk factors than patients who were randomized to placebo.

The authors also reported the results of an analysis that included CV events that had occurred during the treatment period and within 24 months after the closure date for the trial. In this analysis, the overall relative risk of VIOXX compared to placebo did not reach statistical significance.

Merck believes that the limited data from prematurely terminated studies such as ViP and VICTOR need to be interpreted with caution, and that assessments of CV risk with VIOXX must take into account the large amount of randomized, placebo-controlled clinical trial data from the VIOXX research and development program.

### **About Merck**

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**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 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 press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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