Another caution on Vioxx, Celebrex

Danish study suggests increased danger from use of drugs after first heart attack.

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By Aaron Smith, CNN/Money staff writer

DALLAS (CNN/Money) – Merck's Vioxx, Pfizer's Celebrex and similar painkillers increase the risk of death among patients who have already survived a previous heart attack, especially when taken in high doses, according to data released Sunday at the American Heart Association conference here.

Patients who have heart disease should not use these types of drugs, called COX-2 inhibitors, according to Dr. Gunnar Gislason, a research fellow at Bispebjerg University Hospital in Copenhagen and the lead independent researcher in the study, which was funded by the Danish Heart Foundation and the Danish Pharmaceutical Association.

"These results are a cause for concern but not panic," said Gislason. "If you can avoid them, it makes sense to switch to another type of medication if you have cardiovascular disease."

"We have not yet seen the study," said Merck spokesman Chris Loder, who noted that drug safety is typically established through randomized controlled clinical trials, which is different from the type of study conducted by Gislason. "Randomized controlled clinical trials are the gold standard."

Pfizer executives were not immediately available to comment.

This is the latest in a string of bad news regarding the COX-2 drugs, also known as NSAIDs, once a popular class of painkillers that generated billions of dollars in annual sales. The drugs work by blocking COX-2, an enzyme that inflames the joints, and are generally used as arthritis painkillers.

Gislason's study showed that heart disease patients taking more than 25 milligrams daily of Vioxx, also known as rofecoxib, were five times as likely to die as those patients not taking this type of drug. Those taking a 200 mg daily dose of Celebrex, also known as celecoxib, were 4.2 times as likely.

Merck pulled Vioxx off the market on Sept. 30, 2004 after a clinical study suggested an increased risk of heart attacks and strokes in patients who took the drug for at least 18 months. However, Merck says that clinical study did not establish an increase in the risk of death from using Vioxx. Nevertheless since the withdrawal at least 6,500 lawsuits have been filed against Merck by plaintiffs blaming heart attacks on Vioxx, which made $2.5 billion in 2003, its last full year on the market.

Merck (Research) lost the first Vioxx trial in August, a wrongful death suit filed in Houston, and the jury awarded the plaintiff $253 million for the 2001 death of her

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husband. That award would be capped by Texas law at $26 million, according to plaintiff lawyer Mark Lanier. But Merck won its second trial in Atlantic City, N.J., defeating a plaintiff who blamed Vioxx for his non-fatal heart attack in 2001. The next trial begins on Nov. 28 in Houston, where Merck faces its first federal lawsuit, as part of thousands of lawsuits consolidated through federal court.

Pfizer (Research) was able to keep Celebrex, which totaled $3.3 billion in 2004 sales, on the market, but the Food and Drug Administration required the drug to carry a revised label containing a specific warning. Prescriptions have plunged. Gislason's report did not name Bextra, another COX-2 inhibitor from Pfizer that was pulled from the market on April 7, 2005 at the request of the FDA. Bextra sales totaled $1.3 billion in 2004, its last full year on the market.

The Gislason study was based on the medical records of more than 58,000 Danish patients released from hospitals following their first heart attack between 1995 and 2002. Following their release, the patients were treated with Vioxx, Celebrex and "other NSAIDs," according to the researchers.

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