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New Vioxx data suggest heart attack, stroke risks started within months

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TRENTON, N.J. (AP) - Unpublished data from the Merck & Co. (NYSE:MRK) study that led the drugmaker to halt sales of Vioxx appear to show the blockbuster painkiller raised the risk of heart attack and stroke within just a few months - not after at least 18 months' use, as Merck has consistently argued.

The company disputed that Thursday, saying it is "not scientifically appropriate" to draw conclusions based on a key graph in a 108-page report on the data.

The news, first reported by National Public Radio, comes after prominent doctors said Merck misrepresented other data from the same study late last Thursday.

Merck officials said last week that data from a follow-up of patients a year after they stopped taking Vioxx showed heart and stroke risk ended soon after patients stopped taking it - and that patients who later had such complications didn't have a legitimate lawsuit. But several doctors said they believe the data instead showed the heart and stroke risks persisted for at least a year.

The newly public data show the increased cardiovascular risk with Vioxx use likely begins as early as four to six months and then gets bigger, said Dr. Steven Nissen, a Cleveland Clinic cardiologist who heads a huge international study of painkiller safety.

"It didn't really make a lot of sense that nothing happened for 18 months and then all of a sudden you would see a hazard," Nissen said Thursday.

Other doctors concurred.

Because few heart attacks and strokes occurred, Nissen said scientists can't definitively say the painkiller caused the excess complications in the Vioxx group compared to those in the placebo group, but most would interpret it that way.

"There's no 18-month delay until you see harm," said Dr. Curt Furberg, professor of public health science at Wake Forest University School of Medicine.

"This has implications for patients and all the legal cases that are under way," he said, adding, "You're probably at risk the rest of your life."

The study, known by the acronym APPROVe, included 2,586 patients, with half taking Vioxx and half dummy pills for three years. Patients were enrolled from February 2000 to November 2001.

By September 2004, Merck said, the Vioxx group had about twice as many heart attacks and strokes, leading the Whitehouse Station, N.J.-based company to pull the drug from the market then. As lawsuits over Vioxx have topped the 11,500 mark, Merck has insisted there was no increased risk until 18 months - a key argument in its legal strategy.

"The new APPROVe data do not establish that the risk for Vioxx starts earlier than had been previously reported," Merck repeated Thursday in a statement. Merck declined to provide a company official to answer questions on the record.

When the company first published APPROVe data, in February 2005 in the New England Journal of Medicine, it only included complications patients had within 14 days of stopping the drug, even if they stopped early. A key graph in that report didn't show higher risk until after 18 months.

The lead author of that report, Dr. Robert Bresalier of M.D. Anderson Cancer Center, said he is still reviewing the new data but doesn't think the data show that Vioxx risk began earlier. He said the original and new graphs look about the same.

Still, that's not the proper way to report studies, said Dr. Alastair Wood, professor of pharmacology at Vanderbilt University. He said that method would exclude complications suffered by patients who stopped taking Vioxx early because of side effects such as rising blood pressure, then had a heart attack more than two weeks later.

If Merck knowingly excluded those complications, he said, "that's outrageous."

"It's a 'let's hope the referee isn't looking' kind of thing," Wood said.

The complete data follow about 85 per cent of patients throughout the full study, producing a different picture.

A key graph and two related tables in the 108-page report, which Merck supplied to The Associated Press, seem to indicate that within three or four months, a higher risk of heart complications began for patients on Vioxx. The tables show that over the first six months, the Vioxx group had about a 60 per cent higher chance of having a heart attack or stroke.

The risk to the Vioxx group bounces around over the following months, as is common in clinical studies with small numbers of complications, then

rises after 18 months' use.

Merck has submitted the report to the Food and Drug Administration, which has said it is reviewing the new data. A spokeswoman did not return messages Thursday.

Of the six Vioxx lawsuits that have reached verdicts, Merck has lost three.

In trading on the New York Stock Exchange, Merck (NYSE:MRK) shares rose 79 cents to \$35.13 US, as a panel of federal advisers recommended approval of the company's vaccine against cervical cancer, but shares fell 13 cents in after-hours trading.

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