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FDA Reviews Higher Mortality of Stroke Patients Taking Eprex

Three months after the German study began, 16 percent of patients who were treated with the drug Eprex had died, compared with 9 percent who got a placebo, the Food and Drug Administration said in a statement.

The study examined if Eprex could improve brain function in stroke patients, an unapproved use of the drug. The patients were given either relatively high doses of Eprex for three days or a placebo. Most were not anaemic, the FDA said.

Eprex is known generically as epoetin alfa. J&J also sells epoetin alfa under the name Procrit. Amgen Inc sells a version under the name Epogen.

The FDA said it was aware of other clinical trials testing the potential neurological effects of epoetin alfa.

The higher death rate in the German study "suggests the need to closely monitor patients enrolled in other ongoing trials for adverse outcomes and to evaluate whether the potential benefits for enrolled patients outweigh the risks in these trials," the FDA said.

J&J reported last week that early data showed Exprex patients in the German study died more frequently than placebo patients, and said it was doing additional analyses to better understand the findings. The company alerted the FDA to the findings, J&J spokesman Mark Wolfe said on Friday.

J&J shares were down 25 cents at $69.11 on Friday on the New York Stock Exchange.

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