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FDA Expected to Approve Drug Related to Prozac

From Associated Press

INDIANAPOLIS—A cousin to the antidepressant Prozac may receive federal approval before the end of the year for treatment of obesity, representing a new wave of sales growth for this class of drugs.

Prozac, now in its fourth year on the market and approaching \$1 billion in annual sales worldwide, has been dogged for the past year by claims that it causes violent behavior including suicide.

A Harvard researcher's study describing six patients who developed violently suicidal thoughts while treated with Prozac gave rise to more than 50 lawsuits against the drug's manufacturer, Eli Lilly & Co., and helped inspire a media campaign against Prozac by the Church of Scientology, which opposes the practice of psychiatry.

The Food and Drug Administration's rejection Thursday of a Scientology group's bid to have Prozac pulled from pharmacy shelves has been interpreted by drug industry analysts as a sign that the agency will soon quell any lingering doubts about Prozac's safety. As a result, they reason, the door will be open for Lilly to market the drug Lovan to treat obesity.

"I interpret the FDA's recent action as fairly conclusive. I think they'll move rather quickly to

approve Lovan, but it's difficult to say what 'rather quickly' is," said Mark Mayer of the Sanford C. Bernstein & Co. investment firm.

Lilly's stock jumped \$2.50 a share Friday to \$79 in heavy New York Stock Exchange trading, partly on optimism about the future of Prozac and Lovan.

The last FDA hurdle Lilly may face before Lovan is approved, Mayer said, is a meeting later this year of the agency's Psychopharmacological Drugs Advisory Committee to consider whether Prozac and other antidepressants cause suicidal thinking. If Prozac is cleared finally of that possible side-effect, Lovan approval could come quickly, Mayer said.

"We predict Lovan will be approved for obesity in the latter half of 1991," said Ron Nordmann of Paine Webber. "The use of the product for the treatment of obesity has not been associated with violent behavior."

The patients most likely to be prescribed Lovan will be the extremely overweight at risk of contracting diabetes or hypertension because of their obesity, Nordmann said.

Prozac and Lovan are the same chemical compound, fluoxetine. Prozac is available in 20-milligram capsules and Lovan will be prescribed in 60-milligram doses, said Edward West, a spokesman for Lilly, based in Indianapolis.