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## UPDATE 4-FDA OKs J&J's next-generation schizophrenia pill

Wed Dec 20, 2006 4 55 PM ET

(Recasts first sentence, adds interview, analyst comments)

By Julie Steenhuysen

CHICAGO, Dec 20 (Reuters) - U.S. regulators have approved a longer-lasting version of Johnson & Johnson's <JNJ.N> blockbuster schizophrenia drug, Risperdal, the company said on Wednesday.

But while the timing of the approval was as expected, the drug's label included an unexpected warning that it could increase the risk of a potentially fatal heart side effect, raising concerns among investors.

Morgan Stanley analyst Glenn Reicin said the Invega approval should be viewed as a "mixed" event by investors, noting the labeling issues.

Prudential analyst Larry Biegelsen in a research report noted Pfizer's antipsychotic drug, Geodon, carries a similar warning and that "has hampered its uptake." But Biegelsen said the J&J warning was less severe than Pfizer Inc.'s <PFE.N> and said he still believed the drug would be successful.

Invega is designed to deliver paliperidone -- the active ingredient in Risperdal -- through a technology that allows the drug to remain in the body over a longer period of time

Analysts said J&J is hoping to switch a large portion of Risperdal sales to Invega in advance of Risperdal's patent expiration in 2008.

But the drug's label notes a modest increased risk of QT prolongation, a disorder of the heart's electrical system that could lead to life-threatening form of ventricular tachycardia in which the heart is unable to pump blood throughout the body.

"With the exception of Geodon, it does not appear that this QT prolongation warning is present in other similar drugs," Morgan Stanley's Reicin said.

"We continue to believe that Invega will not be viewed as a best-in-class drug since it is relatively undifferentiated from current products and the label warning on the risk of QT prolongation might be used as a marketing weapon by competitors," Reicin said.

### 'APPLES TO ORANGES'

Janssen president Janet Vergis, in an interview, said she does not believe the labeling will present a major hindrance to the drug's acceptance.

She said the drug is the first antipsychotic to be approved since the FDA issued new guidelines in 2005 for a specific type of QT study for all new drug approvals.

"The warnings are very different," added Dr. Mary Kujawa, senior director for Janssen's medical affairs, referring to the Pfizer product.

"The Geodon warning was with prior criteria and considerations. What we are talking about with Invega is the new standard for the FDA. It's like comparing apples to oranges."

Vergis said Invega is the first drug for schizophrenia to include information in its label about improvements in a patient's personal and social functioning, which are key issues for these patients and their families.

Schizophrenia is a chronic, disabling mental disorder that affects more than 2 million Americans. Symptoms include hallucinations, delusions, disordered thinking, movement disorders, social withdrawal and cognitive deficits

Invega is part of a class of drugs known as atypical antipsychotics, which are associated with weight gain and an increased risk of diabetes. Introduced in the 1990s, the drugs now account for some \$10 billion in U.S. sales.

Wall Street analysts have said Invega was key to J&J's drug portfolio.

JP Morgan analyst Michael Weinstein said the approval gives J&J 18 months to market the drug before the start of generic competition for Risperdal. In a note to clients, Weinstein forecast Invega sales of \$488 million in 2007, growing to \$1.78 billion by 2009.

New Brunswick, New Jersey-based J&J will market Invega in the United States through its Janssen LP unit.

The company studied the drug in more than 1,600 patients in 23 countries. Invega improved symptoms compared with placebo in all doses studied. Side effects included restlessness, movement disorders, rapid heart beat and sleepiness.

The FDA said the drugs have an increased rate of death compared with placebo in elderly patients with dementia-related psychosis. The drug is not approved for dementia-related psychosis.

Invega has not undergone rigorous study for longer than six weeks and the FDA recommends that patients who use the drug for extended periods be checked periodically by their doctors.

J&J shares fell 45 cents, or less than 1 percent, to close at \$66.43 Wednesday on the New York Stock Exchange (Additional reporting by Toni Clarke in Boston)

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