Arthritis drugs raise cancer risk in kids: FDA

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By Susan Heavey

WASHINGTON (Reuters) - Blockbuster prescription drugs used to treat rheumatoid arthritis and other conditions can increase the risk of potentially deadly cancer in children and teenagers, U.S. health regulators said on Tuesday in ordering stronger warnings on such medications.

The Food and Drug Administration, which urged greater caution with so-called TNF blockers last September, said an analysis of 48 reported cancer cases in children using the drugs "showed an increased risk of cancer, occurring after 30 months of treatment on average."

Eleven of the reported cases were fatal, the FDA said.

Anti-TNF drugs include Johnson & Johnson's Simponi or golimumab and its Remicade or infliximab; Abbott Laboratories' Humira or adalimumab; UCB SA's Cimzia or certolizumab pegol; and Amgen Inc and Wyeth's Enbrel or etanercept.

Rheumatoid arthritis is an autoimmune disease that can strike young people, causing pain, stiffness and swelling.

It affects about 20 million people worldwide.

The drugs are used to treat other inflammatory conditions, including the bowel disorder known as Crohn's disease.

TNF (tumor necrosis factor) blockers make billions of dollars for manufacturers, but it is unclear how much they earn specifically from sales for children and teens. Not all of the drugs are approved for use in children for all related conditions.

Last year, Abbott's Humira earned $4.5 billion worldwide, while Amgen and Wyeth's Ebrel earned $1.2 billion. J&J's Remicade had 2008 sales of $3.7 billion. Its newer drug, Simponi, was approved earlier this year. UCB's Cimzia, launched in 2008, had about $14.4 million in global sales.

The drugs already carry the strongest warnings possible about the risk of possible serious infections. A new caution about cancer in younger patients will be added to the so-called "black box", the FDA said.

EVALUATING THE CANCER RISK

The FDA said in a statement on its website that its year-long analysis of the increased cancer risk in children showed about half the 48 cases involved lymphoma, which targets the immune system.

Rates for cancer cases with J&J's Remicade "were consistently higher compared to expected background rates for lymphomas and all malignancies," the FDA said. Cancer rates for lymphoma were also higher for Amgen and Wyeth's Enbrel, but rates for all cancers were similar to background rates, the FDA said.

The FDA did not calculate cancer rates for Abbott's Humira and UCB's Cimzia "because of minimal use in pediatric patients." J&J's Simponi was not approved at the time of the time of the analysis.

The FDA said it had "identified new safety information related to the occurrence of leukemia and new-onset psoriasis" that would also be included on the drugs' labeling.

An Abbott spokeswoman said the company would follow the regulator's new warning guidance.

"We will comply with FDA's guidance regarding labeling changes for the anti-TNF class and will continue to monitor the data to ensure patients and physicians have the information they need to make decisions about treatment," Abbott spokeswoman Raquel Powers said.

The FDA said it had reviewed 147 reports of leukemia in adults and children using TNF blockers, including 30 deaths.

While rheumatoid arthritis patients may already be at greater risk for the white blood cell cancer, "there is a possible association between treatment with TNF blockers and the development of leukemia in all patients treated with these drugs," the FDA said.

The FDA also reviewed 69 cases of psoriasis and said it found a possible link between the skin disorder and use of TNF blockers.

Brian Kenney, a spokesman for Johnson & Johnson's Centocor Ortho Biotech Inc unit, which makes Remicade and Simponi, said the company would work with the FDA to adopt the new warnings.

Amgen and Wyeth also said in a statement that they would revise their product warnings and continue evaluating risks and benefits of Enbrel.

(Reporting by Susan Heavey; Editing by David Gregorio)