

## FDA approves first diabetes-cholesterol combo pill

October 7 2011, By LINDA A. JOHNSON , AP Business Writer

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(AP) -- The first combination pill for the millions of people with the dangerous combination of diabetes and high cholesterol won U.S. approval Friday, offering convenience - and savings - to patients taking multiple pills.

Juvisync, a probable blockbuster developed by Merck & Co. Inc., will be launched in a few weeks. It combines Merck's Type 2 diabetes pill Januvia with Zocor, a former Merck blockbuster in the widely used class of cholesterol drugs called statins.

The combination pill will sell for the same price as Januvia alone, about \$215 per month. Generic versions of Zocor cost roughly \$30 a month.

That should make Juvisync attractive for the millions of diabetics currently not taking a statin. Guidelines from the American Diabetes Association recommend that diabetics who have heart disease or are over age 40 take a statin pill daily.

"This provides a way to simplify their regimen and improve adherence," said Dr. Susan Spratt, an endocrinologist at Duke University Medical Center.

Spratt said many diabetes patients are taking six or more pills a day, including different types of pills for diabetes, blood pressure and high cholesterol. It can be hard to consistently take them all at the right time, and even with health insurance, patients' out-of-pocket costs for their

medications and diabetes testing supplies can be very high.

"Anything to reduce the cost is going to be helpful to patients," Spratt said, adding, "When you improve medication adherence, you actually lower health care costs because patients don't end up in the ER or the hospital."

Merck shares rose 37 cents to \$31.79 in late-afternoon trading, after rising nearly 3 percent.

In Type 2 diabetes, the body either does not produce enough of the hormone insulin or does not use it efficiently, allowing excess sugar, or glucose, to accumulate in the blood. Over time, that damages blood vessels and crucial organs.

Many of the more than 25 million U.S. diabetes patients also have high cholesterol, partly because both conditions often are linked to being overweight. The combination increases risk of heart disease, stroke, kidney disease and other chronic conditions. Diabetics also are at risk of blindness, amputations from wounds that do not heal and heart attacks.

Despite those dangers, Merck scientists estimate that up to 4 million diabetes patients over 40 are not following the medication recommendation.

"Perhaps one third of the nation's eligible patients with type 2 diabetes are not being treated with a statin, so here's a convenient tool for doctors to target glucose as well as cholesterol levels," Dr. Sethu Reddy, Merck's director of clinical affairs for diabetes, said in a statement.

Juvisync will be available in six different dosage strengths, to accommodate patients with varying levels of cholesterol and diabetes. Common side effects of the drug include stuffy nose and sore throat,

headache, muscle and stomach pain.

The approval revives Zocor, which had been Merck's top-selling medicine before it got generic competition in June 2006. It's now available in nearly a dozen generic forms as simvastatin.

Januvia, Merck's third-best-selling drug, was approved in October 2006. It was the first diabetes drug in a new class called DPP-4 inhibitors that now includes Bristol-Myers Squibb Co.'s Onglyza and Tradjenta, made by Eli Lilly & Co. and Boehringer Ingelheim.

The drugs work by making the body produce more insulin after meals, to reduce levels of glucose in the blood, and by limiting the amount of glucose made by the liver.

Januvia brought in \$1.5 billion in the first six months of this year and had sales of \$2.4 billion last year. Merck already sells a pill that combines Januvia with a widely used generic diabetes pill, metformin. That combo pill, called Janumet, had sales of \$626 million in the first half of this year.

With Merck's top seller, asthma and allergy drug Singulair, getting generic competition next August, the Januvia franchise becomes even more important for the company, which is the world's third-biggest drugmaker by revenue.

Merck, based in Whitehouse Station, N.J., is planning to seek approval of Juvisync in many other countries in the near future, according to spokeswoman Pam Eisele.

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Citation: FDA approves first diabetes-cholesterol combo pill (2011, October 7) retrieved 29 April 2024 from

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