

# US probes new pancreas risks with diabetes drugs (Update)

March 14 2013, by Matthew Perrone

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The U.S. Food and Drug Administration is looking into new evidence that suggests a group of recently approved diabetes drugs can increase the risk of pancreatitis and other problems.

The agency said Thursday samples of pancreas tissue taken from a small number of patients showed inflammation and cellular changes that often precede cancer. Academic researchers took the samples from diabetes patients who were taking the new medications, after they died from various causes.

Details of the research have not yet been published, but the agency said in an online statement it is seeking more information.

While the FDA has issued previous alerts about the pancreatitis risk, the agency had not notified the public about pre-cancerous cell changes seen with the drugs.

For now, regulators say they are still investigating the issue.

"FDA has not concluded these drugs may cause or contribute to the development of pancreatic cancer," the agency said in an online statement. "At this time, patients should continue to take their medicine as directed until they talk to their health care professional."

The drugs under review come from a wave of recently approved diabetes medications, including Merck's Januvia and Janumet, Danish-based

Novo Nordisk's Victoza and Bristol-Myers Squibb's Byetta and Bydureon, among others. All the drugs mimic natural hormones that the body usually produces to spur insulin production after a meal.

Citi Investment Research analyst Andrew Baum told investors the investigation would likely have "minimal impact" on drug sales. Similar investigations in recent years have not resulted in safety restrictions, he says.

"We believe that the likely worst case for the market incumbents is that the FDA could add additional warnings about increased risk of pancreas-related adverse events" Baum stated in a research note.

People with type 2 diabetes are unable to properly break down carbohydrates, either because their bodies do not produce enough insulin or because they've become resistant to the hormone, which controls blood sugar levels. These patients are at higher risk for heart attacks, kidney problems, blindness and other serious complications.

Many diabetics require multiple drugs with different mechanisms of action to control their blood sugar levels.

With more than 25 million people living with diabetes in the U.S., some of the world's biggest drugmakers have launched new treatments in recent years, though safety questions have emerged.

The FDA previously added information about cases of pancreatitis, some of them fatal, to the labels of Byetta in 2007, and Januvia and Janumet in 2009.

A recent study of insurance records found that use of those drugs could double the risk of developing acute pancreatitis, according to the FDA.

Januvia is a once-a-day pill. Janumet combines the drug with metformin, a decades-old drug commonly prescribed for diabetes. Byetta is a twice-a-day injection originally developed by Amylin Pharmaceuticals. Bristol-Myers acquired the drug last year, along with the newer formulation Bydureon, which is taken once-a-week.

Byetta and Bydureon are part of a drug class that mimics the GLP-1 hormone, triggering insulin production after a meal.

Januvia and Janumet work by blocking the DPP-4 enzyme, which spurs release of more insulin from the pancreas. Those drugs brought in a total of about \$5.75 billion last year, making them Merck's biggest franchise.

The pancreas produces various hormones, including insulin, that help the body break down sugar. Pancreatitis causes an inflammation of the organ and can lead to fatal complications, including difficulty breathing and kidney failure.

Shares of Merck & Co. Inc. fell 32 cents to \$44.27. Shares of Bristol-Myers Squibb Co. declined 1 cent to \$38.48.

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