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US panel backs novel diabetes pill from J&J (Update)

January 10 2013

A panel of U.S. health experts ruled Thursday that an experimental diabetes drug from Johnson & Johnson is safe and effective, though lingering safety questions must be tracked over the long term.

The Food and Drug Administration's panel of diabetes experts voted 10-5 in favor of J&J's canagliflozin to treat Type 2 diabetes. The drug is part of a new class of medications that work by increasing the levels of blood sugar excreted via urine.

Panelists said the drug could be useful in combination with existing diabetes medications. However, they raised concerns about low levels of heart attack, stroke and urinary tract infections seen in the first year of testing. The experts said those infections could be especially harmful to patients with kidney damage, a common side effect of diabetes.

Almost all panelists recommended that the company be required to track those problems over the long term to tell whether they get worse.

"There are definitely benefits to this drug, there are also risks," said Dr. Abraham Thomas of the Henry Ford Hospital. "I still have concerns, as many other do."

In recent years, the FDA has required companies developing diabetes drugs to track cardiac side effects in patient testing. That's because diabetes medicines are taken daily for many years, and one former blockbuster, Avandia, was linked to higher heart attack risks. In 2010,

the FDA restricted Avandia's use to patients not helped by any other diabetes treatments, and European regulators barred all sales of Avandia.

J&J is studying canagliflozin in nine studies enrolling more than 10,000 patients. It notes this is the largest research effort of its kind submitted to FDA for a diabetes drug.

If the FDA approves the New Brunswick, New Jersey company's drug, it would be the first in a new class medicines called SGLT2 inhibitors.

The agency rejected another experimental drug in the SGLT2 class, dapagliflozin from partners Bristol-Myers Squibb Co. and AstraZeneca PLC, a year ago. The FDA cited concerns about possible liver damage and elevated rates of bladder and breast cancer.

The FDA has set a target date of March 31 to decide whether to approve U.S. sales of canagliflozin. Johnson and Johnson would sell it under the brand name Invokana.