US OKs first-of-its-kind diabetes drug (Update)

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The U.S. Food and Drug Administration on Friday approved a first-of-its-kind diabetes drug from Johnson & Johnson that uses a new method to lower blood sugar—flushing it out in patients' urine.

The agency cleared J&J's Invokana tablets for adults with Type 2 diabetes. The once-a-day medication works by blocking the kidneys from reabsorbing sugar, which occurs at higher levels in patients with diabetes than in healthy patients. Regulators highlighted the drug as the first in a new class of medications that could help address the growing U.S. diabetes epidemic.

Analysts estimate Invokana could eventually grow into a blockbuster drug, generating more than $1 billion in sales annually for J&J.

People with type 2 diabetes are unable to properly break down carbohydrates, either because their bodies do not produce enough insulin or have 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. Diabetics often require multiple drugs with different mechanisms of action to control their blood sugar levels.

Invokana differs from older drugs that work by shrinking the amount of sugar absorbed from food and stored in the liver. The most common side effects of Invokana are yeast infections and urinary tract infections, due to the higher amounts of sugar passing through a patient's urine. The drug also can cause a sudden drop in blood pressure when a patient stands up, which can lead to dizziness or fainting, according to the FDA.

The FDA said it approved the drug based on nine studies involving more than 10,000 patients. The studies showed that Invokana, both alone and in combination with other diabetes drugs, helped control blood sugar levels.

"We continue to advance innovation with the approval of new drug classes that provide additional treatment options for chronic conditions that impact public health," said Dr. Mary Parks, director of the FDA's division of endocrinology products.

Regulators are requiring Johnson & Johnson to conduct five follow-up studies to assure the drug's safety. The company will track rates of heart problems, cancer, pancreatitis and liver abnormalities, among other issues.

In recent years, the FDA has required companies developing diabetes drugs to closely monitor all heart-related side effects in patients. That's because diabetes medicines are taken daily for many years, and one former blockbuster, GlaxoSmithKline PLC's 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 banned sales of Avandia completely.

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