

# FDA Approves a First-in-Class Diabetes Drug: Invokana

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The U.S. Food and Drug Administration (FDA) has approved the first in a new class of medications to treat type 2 diabetes, under the condition that the drug manufacturer conduct additional research, The New York Times reports. The FDA approved Invokana (canagliflozin), which is a sodium glucose co-transporter 2 (SGLT2) manufactured by Janssen Pharmaceuticals, a division of Johnson & Johnson. Invokana is the only approved diabetes therapy that does not affect insulin. Instead, it operates by impeding glucose's reabsorption into the kidney, which increases excretion of the sugar directly into the urine.

Type 2 diabetes disproportionately affects people living with HIV and its prevalence among this group is on the rise according to recent research.

The FDA ordered Janssen to conduct five post marketing studies: a bone safety trial; a cardiovascular outcomes study; two pediatric trials; and a program to monitor for cancers, severe pancreatitis, severe high blood pressure, sensitivity to light, liver abnormalities and adverse effects on pregnancy.

The agency granted approval for Invokana based on nine clinical trials involving more than 10,000 participants with type 2 diabetes. As compared with a placebo, the drug demonstrated improvement in fasting plasma glucose and glycated hemoglobin (HbA1c) levels. It also proved non-inferior to the diabetes medications Amaryl (glimepiride) and Januvia (sitagliptin).

Common side effects included vaginal yeast infections and urinary tract infections.

To read the New York Times story, [click here](#).

To read the FDA release, [click here](#).

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