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FDA approval for BI/Lilly's diabetes combo pill

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The US Food and Drug Administration (US FDA) has approved Synjardy (empagliflozin and metformin hydrochloride) tablets, from Boehringer Ingelheim Pharmaceuticals, and Eli Lilly and Company, for the treatment of adults with type 2 diabetes (T2D).

SYNJARDY is the third product containing empagliflozin to be approved by the FDA, following Jardiance (empagliflozin) and Glyxambi(empagliflozin/linagliptin).

SYNJARDY is a combination of empagliflozin and metformin - two medicines with complementary mechanisms of action - to help control blood glucose in people with T2D. Empagliflozin, a sodium glucose co-transporter-2 (SGLT2) inhibitor, removes excess glucose through the urine by blocking glucose re-absorption in the kidney. Metformin, a commonly prescribed initial treatment for T2D, lowers glucose production by the liver and its absorption in the intestine.

"SYNJARDY is now the fifth FDA-approved medicine to emerge from the BI-Lilly Diabetes alliance pipeline in the last four years," said Mr Paul Fonteyne, president and CEO, Boehringer Ingelheim Pharmaceuticals. He added, "No two people with diabetes are alike, and every experience is different. Our alliance is proud to offer a diverse portfolio of treatments that can help patients throughout their diabetes journey."

SYNJARDY is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2D who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with empagliflozin and metformin. SYNJARDY is not for the treatment of type 1 diabetes or diabetic ketoacidosis.

The SYNJARDY label contains a boxed warning for the risk of lactic acidosis, a serious metabolic complication that can occur due to metformin accumulation during treatment with SYNJARDY.

The FDA approval of SYNJARDY is based on results from multiple clinical trials examining the co-administration of empagliflozin and metformin, alone or in combination with sulfonylurea, in the treatment of adults with T2D.

SYNJARDY was also recently approved by the European Medicines Agency in May 2015.