FDA approves Jentadueto™ (linagliptin/metformin hydrochloride) tablets for the treatment of adults with Type 2 Diabetes

Boehringer Ingelheim

Ingelheim, Germany and Indianapolis, USA, 31 January, 2012 – Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company (NYSE: LLY) have announced that the U.S. Food and Drug Administration (FDA) has approved Jentadueto™ (linagliptin/metformin hydrochloride) tablets, a new tablet combining the dipeptidyl peptidase-4 (DPP-4) inhibitor, linagliptin, and metformin. [1] Linagliptin/metformin hydrochloride (HCl) provides a new, single-tablet treatment option, taken twice-daily, for adults with Type 2 Diabetes who need to improve control of their blood glucose. [1] Linagliptin (5 mg, once-daily) is marketed in the U.S. as Tradjenta™ (linagliptin) tablets, as Trajenta™ across Europe and Canada, and Trazenta™ in Japan, as well as in further markets. [2,3]

Linagliptin/metformin HCl is a prescription medication used along with diet and exercise to improve glycaemic control in adults with Type 2 Diabetes when treatment with both linagliptin and metformin is appropriate. At the maximum dose, linagliptin/metformin HCl demonstrated placebo-corrected reductions in haemoglobin A_{1c} (HbA_{1c} or A1C) levels of up to 1.7 percent (+0.1 percent for placebo and -1.6 percent for linagliptin/metformin HCl). A1C is measured in people with diabetes to provide an index of blood glucose control for the previous two to three months. Linagliptin/metformin HCl did not cause any meaningful change in body weight. Linagliptin/metformin HCl can be used alone or in combination with a sulphonylurea, a commonly prescribed medication for Type 2 Diabetes. Linagliptin/metformin HCl are not for the treatment of Type 1 Diabetes or diabetic ketoacidosis (increased ketones in the blood or urine). It has not been studied in combination with insulin. The linagliptin/metformin HCl 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 linagliptin/metformin HCl. [1]

SOURCE [1]

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http://www.chem.info/news/2012/01/fda-approves-jentadueto%E2%84%A2-linagliptin/metformin-hydrochloride-tablets-treatment-adults-type-2-diabetes?qt-most_popular=1

Links:
[1] http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2012/31_january_2012_diabetes.html