Linagliptin recommended for approval in the treatment of type 2 diabetes in Europe

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RIDGEFIELD, Conn. and INDIANAPOLIS, June 24, 2011 /PRNewswire/ -- Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY [1]) today received a positive opinion from the European Medicines Agency's (EMA) medicinal committee recommending approval of linagliptin, 5 mg, film-coated tablets (to be marketed under the trade name Trajenta® in Europe) for the treatment of adults with type 2 diabetes. If adopted by the European Commission, linagliptin will be the only DPP-4 inhibitor approved at one dosage strength for patients with type 2 diabetes in Europe. Linagliptin, 5 mg, is marketed under the trade name Tradjenta™ (linagliptin) tablets in the U.S. and was approved by the U.S. Food and Drug Administration (FDA) in May 2011 to be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. Linagliptin should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine). It has not been studied in combination with insulin.

The Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of linagliptin as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment. Linagliptin is also recommended for approval in combination with metformin and metformin plus sulfonylurea. Data showed linagliptin plus metformin reduced hemoglobin A1C (HbA1C or A1C) levels by a mean of 0.6 to 0.7 percent (compared to placebo). A1C is measured in people with diabetes to provide an index of blood glucose control for the previous two to three months. It is used as a marker to determine the efficacy of glucose-lowering therapies.

"This will be an important step forward in the management of type 2 diabetes in Europe," said Prof. Anthony Ba
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