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Singapore: Boehringer Ingelheim and Eli Lilly and Company received approved from the US FDA for a supplemental new drug application (sNDA) for Tradjenta (linagliptin) tablets for use as add-on therapy to insulin.

Tradjenta is a prescription medication used along with diet and exercise to lower blood sugar in adults with type 2 diabetes, and can be used as monotherapy or in combination with other commonly prescribed medications for type 2 diabetes, such as metformin, sulfonylurea, pioglitazone or insulin. Tradjenta should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine).

The FDA's decision is based on data from a 52-week, phase III trial demonstrating the efficacy of Tradjenta in combination with insulin (with or without metformin and/or pioglitazone). The trial results showed adding Tradjenta to insulin produced better glucose control than insulin alone, with similar incidence of hypoglycemia (low blood sugar) in both treatment groups. Tradjenta belongs to a class of prescription medications called dipeptidyl peptidase-4 (DPP-4) inhibitors and is the first member of its class to be approved at one dosage strength (5 mg, once-daily).

Additionally, the FDA-approved label includes a clinical study in people with severe chronic renal impairment. Data from a 52-week, double-blind, randomized, placebo-controlled trial showed that use of TRADJENTA 5 mg plus other glucose-lowering therapies in this patient population provided a statistically significant improvement in glycated hemoglobin (HbA1c or A1C) as compared to placebo (placebo-adjusted reduction of 0.7 percent).

Dr John Smith, senior VP, clinical development and medical affairs, Boehringer Ingelheim, said that, "Many people with type 2 diabetes taking insulin also require additional medication. With today's FDA decision, Tradjenta can be an effective add-on therapy with a demonstrated safety profile to help adult patients on insulin to improve their blood sugar control. Tradjenta is the only once-daily, one-dose drug in its class without the need for dose adjustment regardless of declining renal function or hepatic impairment."