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ASIA EDITION

Linagliptin efficacy further established in specific patient populations

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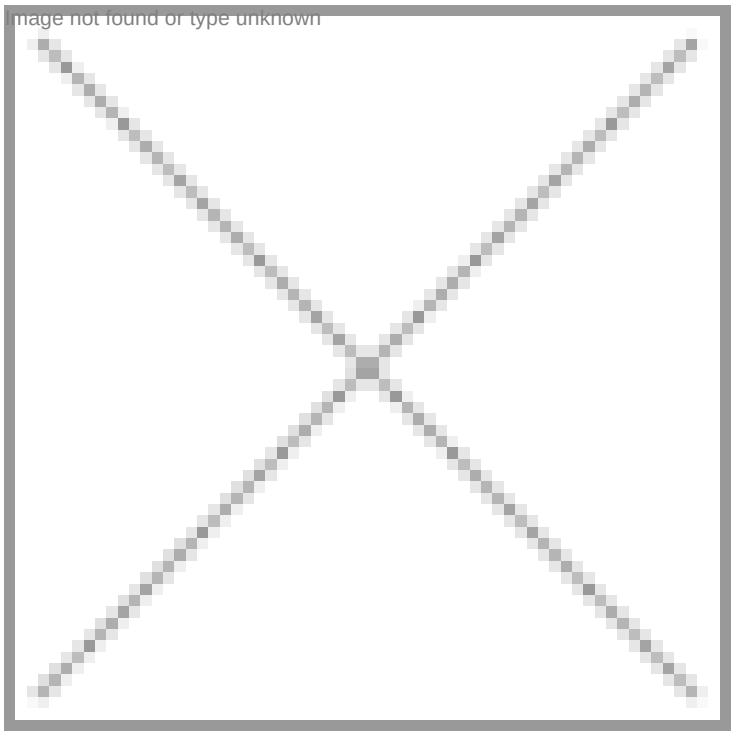

Seoul: Boehringer Ingelheim and Eli Lilly & Company have announced new data that reinforces the efficacy and tolerability of linagliptin in patients with Type 2 Diabetes (T2D) and liver disease, as well as in Asians with T2D (65 years and older). The data adds to a growing body of clinical evidence supporting the use of linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor from Boehringer Ingelheim (BI) and Eli Lilly and Company, in a broad range of adults with T2D.

The data was shared at the 2013 International Conference on Diabetes and Metabolism & 5th Asian Association for the Study of Diabetes (AASD) Annual Scientific meeting held in Seoul, South Korea.

The US Food and Drug Administration (FDA), European Medicines Agency (EMA), Japan Pharmaceuticals and Medical Devices Agency (PMDA) and several other regulatory authorities worldwide have approved linagliptin for the treatment of adults with T2D as monotherapy or in combination with metformin, metformin + sulphonylurea, and as add-on therapy to insulin. With linagliptin, no dose adjustment is required regardless of renal function or hepatic impairment.

Adults with T2D, aged 65 years or older, and those with pre-existing liver and biliary disease are characterized by limited treatment options. With the rate of T2D rapidly growing in Asia, and the prevalence of T2D and hepatobiliary diseases being high, especially in Asian countries, effective and safe treatment options are increasingly becoming a priority. Given the major elimination of linagliptin via the entero-hepatic system, further characterizing the efficacy and safety of linagliptin in T2D patients with liver and biliary complications becomes particularly important.

An estimated 371 million people worldwide have Type 1 and Type 2 Diabetes. Type 2 Diabetes is the most common type, accounting for an estimated 90 percent of all diabetes cases. Fifty percent of these patients are in Asia with China and India accounting for over 90 percent of the diabetes patients in Asia. Globally, $471 billion was spent as healthcare expenditure due to diabetes and 4.8 million lost their lives to this disease. Diabetes is a disease that occurs when the body either does not properly produce, or use, the hormone insulin.

Linagliptin (5 mg) is marketed in Europe as Trajenta and in the US as Tradjenta, as a once-daily tablet that is used along with diet and exercise to improve glycaemic control in adults with T2D. Linagliptin is not to be used in patients with Type 1 Diabetes or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine).

Diabetes pioneer Eli Lilly & Company, and Ingelheim, Germany-headquartered Boehringer Ingelheim had entered into an alliance in January 2011 that centres on three compounds representing several of the largest diabetes treatment classes, in an effort to address the unmet need in diabetes therapy.

Some data highlights from the 2013 AASD Annual Scientific Conference

Efficacy and tolerability in people with T2D and previous/currentliver and biliary disease
In a pooled analysis of 17 double-blind placebo controlled randomized clinical trials investigating the efficacy and tolerability of linagliptin in people with T2D and self-reported previous/currentliver and biliary disease, results showed:

- · Linagliptin demonstrated a statistically significant placebo-adjusted reduction in HbA1c of 0.52 and 0.62 percent in patients with- and without hepatobiliary disorders, respectively, from baseline to 24 weeks.
- · Overall incidence of adverse events (AEs) was similar for hepatobiliary (65.1 percent - linagliptin; 68.0 percent - placebo) and non-hepatobiliary patients (56.7 percent - linagliptin; and 62.0 percent - placebo).
- · Rates of serious AEs were 7.9 percent vs. 9.9 percent (linagliptin and placebo, respectively) in the hepatobiliary group, and 4.7 percent vs. 6.6 percent, (linagliptin and placebo, respectively) in the non-hepatobiliary group.
- · Fewer patients in the linagliptin group experienced drug related AEs than placebo (12 percent vs. 15.3 percenthepatobiliary; 11.6 percent vs. 13.6 percent non-hepatobiliary); and hypoglycaemia was less frequent with linagliptin versus placebo (12.2 percent vs. 19.2 percenthepatobiliary; 11.9 vs. 14.8 non-hepatobiliary).

Efficacy and safety in Asian elderly patients with T2D
In a second pooled analysis investigating the efficacy and safety of linagliptin (as monotherapy or in combination with common anti-hyperglycaemic drugs) in Asian people aged 65 years or older with uncontrolled T2D, results showed:

- · Linagliptin demonstrated a statistically significant reduction in HbA1c of 0.90 percent, compared to a 0.08 percent reduction with placebo, resulting in a treatment difference of 0.82 percent after 24 weeks.
- · Overall incidence of adverse events (AEs) or serious adverse events (SAEs) with linagliptin was similar to placebo (AE 53.6 percentvs 61.9 percent, and SAE 4.5 percent vs. 6.9 percent respectively).
- · Drug-related AEs were lower in the linagliptin arm than with placebo (12.6 percent vs. 17.5 percent, respectively); as was the occurrence of investigator defined hypoglycaemia (9.5 percent vs. 18.1 percent, respectively).
- · The incidence of symptomatic hypoglycemia events was similar to placebo (1.1 percent in linagliptinvs 1.5 percentin placebo) when patients were not on insulin or sulphonylurea background therapy.