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Boehringer, Eli Lilly to evaluate Trajenta for type 2 diabetes

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Singapore: Boehringer Ingelheim and Eli Lilly have initiated phase IIIb trial to evaluate the glycaemic efficacy and safety of linagliptin in type 2 diabetes patients with prevalent albuminuria, and urinary albumin-to-creatinine (UACR) ratio 30-3000 mg/g creatinine, in addition to current standard therapy for diabetic nephropathy.

"With linagliptin, no dose adjustment is required even for patients with declining renal function", said Professor Per-Henrik Groop, chief physician at Nephrology division, Helsinki University Central Hospital, Finland, and principal investigator of the MARLINA trial. "What is of particular interest is that this study will evaluate the glycaemic efficacy and safety of linagliptin therapy in patients with type 2 diabetes whose kidneys are excreting significant amounts of albumin, a marker of both, kidney damage as well as an overall increased cardiovascular risk."

The primary endpoint of the trial is the change from baseline in HbA1c after 24 weeks of treatment. The study is expected to complete in 2014.

"The initiation of this new trial reinforces our ongoing commitment to the field of type 2 diabetes," said Professor Klaus Dugi, corporate senior vice president-Medicine, Boehringer Ingelheim. "It is important to find more treatment options, especially for those patients who are at risk of renal and cardiovascular disease and who have limited choices of treatment."

The US Food and Drug Administration (FDA), European Medicines Agency and other regulatory authorities worldwide approved linagliptin for the treatment of adult patients with Type 2 diabetes as monotherapy or in combination with metformin, metformin plus sulphonylurea, and as add-on therapy to insulin.