

## BI reveals novel findings on Asian adults with T2D

30 June 2020 | News

**In a sub-analysis of the CAROLINA® cardiovascular outcome trial, linagliptin demonstrated no increased cardiovascular risk versus glimepiride in Asian adults with type 2 diabetes and high cardiovascular risk**



Boehringer Ingelheim have announced the results of a sub-group analysis from the CAROLINA® cardiovascular outcome trial focusing on Asian adults with type 2 diabetes mellitus and elevated cardiovascular risk.

CAROLINA® (CARdiovascular Outcome study of LINAgliptin versus glimepiride in patients with type 2 diabetes) is a multi-national, randomized, double-blind, active-controlled clinical trial.

The findings, published in *Diabetology International*, demonstrated that linagliptin did not increase cardiovascular risk in this population versus glimepiride, and were in line with the results of the overall CAROLINA® study population.

The prevalence of type 2 diabetes mellitus has increased rapidly in recent years within Asia. In 2019, the International Diabetes Federation estimated that over half (251 million) of the 463 million people globally with diabetes were in Southeast Asia and the Western Pacific.

The prespecified CAROLINA® sub-group analysis comprised 933 adults from Asia, 15.5% of the overall 6,033 participants in the CAROLINA® study.

Amongst the Asian participants in the CAROLINA® study, treatment with linagliptin demonstrated a lower rate of hypoglycemia and lower risk for weight gain compared to treatment with glimepiride. Hypoglycemia of any severity occurred in 13.1% of Asian patients treated with linagliptin compared to 42.1% of those treated with glimepiride.

Linagliptin showed modest weight reduction between the two treatment groups, with an average mean difference of –1.82 kg compared to glimepiride.

CAROLINA® and CARMELINA® make up the two cardiovascular outcome trials for linagliptin, providing one of the most comprehensive datasets on the long-term safety of a DPP-4-inhibitor.

A sub-analysis of the CARMELINA® trial, published in *Diabetology International* in October 2019, demonstrated that linagliptin did not increase risk for cardiovascular or kidney events compared to placebo in Asian adults with type 2 diabetes

at high risk for heart and/or kidney disease. These results are consistent with findings in the overall CARMELINA® study population.

“When the CARMELINA® and CAROLINA® trials were first published, they demonstrated linagliptin’s long-term safety profile across a broad range of patients with type 2 diabetes,” said Waheed Jamal, MD, Corporate Vice President and Head of CardioMetabolic Medicine, Boehringer Ingelheim. “These region-specific, sub-analyses will give clinicians confidence when choosing the most appropriate glucose-lowering treatment for their patients.”

These trials demonstrate the cardiovascular and renal safety profile of linagliptin in a broad range of Asian adults with type 2 diabetes.