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Albiglutide reduces cardiovascular events in patients with type 2 diabetes and existing cardiovascular disease

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New research presented at this year's annual meeting of the European Association for the Study of Diabetes (EASD) and published in *The Lancet* shows that treatment with albiglutide (a type of drug called a glucagon-like peptide 1 receptor agonist) results in fewer cardiovascular events in people with type 2 diabetes and existing cardiovascular disease than treatment with placebo.

The GSK sponsored Harmony-Outcomes study was led by Professor Stefano Del Prato, Department of Clinical & Experimental Medicine, University of Pisa, Italy and Professor John McMurray, British Heart Foundation Cardiovascular Research Centre, University of Glasgow, UK.

This randomised, double-blind, placebo-controlled, event-driven trial took place at 610 sites in 28 countries. Patients with type 2 diabetes and cardiovascular disease were randomly assigned to once-weekly subcutaneous injection of albiglutide (30 mg to 50 mg) or matching placebo in addition to standard care. The authors hypothesised that albiglutide would be non-inferior to placebo for the primary outcome of first occurrence of cardiovascular death, myocardial infarction, or stroke.

Overall, 9463 participants were followed for a median of 1.6 years. The pre-specified primary combined outcome occurred in 338 of 4731

patients (7.1%; 4.6 events per 100 person-years) in the albiglutide group and in 428 of 4732 patients (9.0%; 5.9 events per 100 person-years) in the placebo group, meaning a 22% reduced risk of this outcome in the albiglutide group (a statistically significant result showing albiglutide to be superior to placebo).

The incidence of acute pancreatitis (albiglutide 10 patients and placebo 7 patients), pancreatic cancer (6 and 5), medullary thyroid carcinoma (zero cases in both groups), and other serious adverse events did not differ significantly between the two groups.

The authors say: "In patients with type 2 diabetes and cardiovascular disease receiving standard care, addition of once-weekly albiglutide reduced the risk of the primary composite outcome—death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke—by 22%, compared with the addition of placebo. Overall, the number of patients who would need to be treated with albiglutide to prevent one event over a median of 1.6 years was 50."

Professor Stefano Del Prato added "We are very excited by these results which add to the evidence that certain GLP-1-receptor agonists reduce cardiovascular events in patients with type 2 diabetes. This new therapeutic approach offers physicians a further means of reducing the most common and deadly complication faced by our patients with type 2 diabetes."

Professor McMurray added "These are impressive findings, with a reduction in risk at least as large as that obtained with traditional cardiovascular drugs and clearly an important addition to the therapeutic approaches available to tackle this problem."

The authors conclude: "In summary, when added to standard care in patients with type 2 diabetes and established cardiovascular disease, the

long-acting GLP-1-receptor agonist albiglutide reduced the risk of major adverse cardiovascular events with acceptable tolerability and safety. These findings provide more evidence that certain GLP-1-receptor agonists can improve cardiovascular outcomes in patients with type 2 diabetes."

Dr. John Lepore, Senior Vice President R&D Pipeline, GSK said: "We would like to thank all the investigators and patients who participated in this study. Harmony-Outcomes was an important study for us to complete to generate new data and insights about the role of the GLP-1 receptor agonist class in the management of patients with diabetes and cardiovascular disease. GSK continued to invest in this study following a decision last year to cease all other activities on albiglutide, and we continue to explore opportunities to divest this medicine to a company with the right expertise and resources to realise its full potential for patients."

More information: *The Lancet* (2018). www.thelancet.com/journals/lan … (18)32261-X/fulltext

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