

## MSD's cardiovascular safety trial of JANUVIA (sitagliptin), met primary endpoint in patients with type 2 diabetes

MSD, known as Merck in the United States and Canada, recently announced the primary results of the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS), a placebo-controlled study of the cardiovascular (CV) safety of MSD's DPP-4 inhibitor, JANUVIA® (sitagliptin).

The TECOS cardiovascular safety trial was an event-driven study designed to assess the long-term CV safety of the addition of sitagliptin to usual care, compared to usual care without sitagliptin, in patients with type 2 diabetes and established CV disease.

More than 14 735 patients enrolled on the study from 38 countries and was led by independent academic research collaboration between the University of Oxford Diabetes Trials Unit and the Duke University Clinical Research Institute, and was sponsored by MSD. Among the key findings, it was evident that there was no increase in CV-related deaths or hospitalisation for heart failure in the Sitagliptin group versus placebo.

'Patients with type 2 diabetes may need antihyperglycaemic medicines to help control their blood glucose levels. Because these patients are at increased risk for cardiovascular complications, understanding the cardiovascular safety of these medicines is important,' said study co-chair Rury Holman, Professor of Diabetic Medicine and Diabetes Trials Unit Director, University of Oxford. 'The results from TECOS showed that sitagliptin did not increase the risk of cardiovascular events in a diverse group of patients with type 2 diabetes at high cardiovascular risk.'

Overall, the primary endpoint occurred in 11.4% (n=839) of sitagliptin-treated patients compared with 11.6% (n=851) of placebo-treated patients in the Intention-to-Treat (ITT) analysis, and in 9.6% (n=695) of patients in both the sitagliptin and placebo groups in the Per Protocol (PP) analysis.

In addition, there was no increase in hospitalisation for heart failure, and rates of all-cause mortality were similar in both treatment groups, which were two key secondary endpoints.

'We believe the results of TECOS provide important clinical information about the cardiovascular safety profile of sitagliptin,' said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. 'The TECOS CV safety trial reflects the best efforts of clinical scientists at the University of Oxford, the Duke Clinical Research Institute and MSD on behalf of patients around the world who suffer from type 2 diabetes.'



## Focusing on healthy eating for Diabetes Day 2015

The focus on this year's World Diabetes Day (WDD) is healthy eating which is a key factor in the fight against the condition, it has been announced.

This year's campaign entitled, 'Act Today to Change Tomorrow' is also hoping to raise awareness of the importance of early detection,

and the blue circle symbol will be used across social media to mark and promote WDD.

It is led by the International Diabetes Federation (IDF) and runs all year round, but is celebrated on 14<sup>th</sup> November.

This year's message is to promote the importance of healthy eating which can help manage all types of diabetes.

According to the IDF, a healthy diet containing leafy vegetables, fresh fruit, whole grains, lean meat, unsweetened yogurt, and nuts can help reduce a person's risk of type 2 diabetes and reduce complications in people with type 1.

On 12<sup>th</sup> November 2015, two days before WDD, the IDF will release the Diabetes Atlas, which is the authoritative resource on the global burden of diabetes.

There are many ways people can participate in this year's campaign, including taking a blue circle selfie and sharing it on social media, or organising a diabetes fair. IDF are asking anyone who is participating in a WDD campaign to get in touch.

For more details visit <http://diabetestimes.co.uk/diabetes-day-2015-to-focus-on-healthy-eating/#sthash.lAc8vjpw.dpuf>

## Digital tools provide limited support for diabetes



A new study reports that digital tools to monitor diabetes have short-lived effects on users. While a plethora of apps and online resources are

available for self-care, the knowledge provided often doesn't translate to behavioural changes.

Chronically ill patients can manage the disease using personalised programmes on computers and smartphones that can help reduce healthcare costs.

However, *the Cochrane Library* report explains such tools bring little improvement to long-term issues like depression, blood pressure, weight or quality of life.

Researchers reviewed data from more than 3500 people with type 2 diabetes who used computers or mobile phones to self-manage their disease. Though there were significant benefits for controlling blood glucose levels, they tapered off after six months.

The digital tools evaluated in the study include stat-taking, online peer support, goal setting and glucose indicators. Overall, while evidence suggests they do help provide a better understanding of the disease, they don't promote changes in diet and exercise.

'Effective self-management is a complex task that may require changes to many aspects of people's lives,' said lead researcher Kingshuk Pal. 'Any intervention to help that process needs to support sustained behavior change in different areas like eating habits, physical activity or taking medication regularly, and provide emotional support.'