

# In brief

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## New drugs for diabetes

A new DPP-4i for the management of type 2 diabetes, alogliptin (Vipidia®) has been launched by Takeda in the UK following data from EXAMINE, an outcome trial conducted in high risk acute coronary syndrome patients (see *Br J Cardiol* 2013;4:131) where the drug significantly reduced glucose levels and also demonstrated cardiovascular safety.

Alogliptin and the fixed-dose combination product alogliptin and metformin (Vipdomet®) are now available in the UK. Alogliptin is licensed for the treatment of type 2 diabetes mellitus in adults aged 18 years and older to improve glycaemic control in combination with other glucose-lowering agents including insulin when these, together with diet and exercise, do not provide adequate glycaemic control.

Draft guidance issued from the National Institute for Health and Care Excellence (NICE) has recommended canagliflozin as a treatment option, in combination with other agents for the management of diabetes.

Canagliflozin (Invokana®) produced by Janssen Pharmaceuticals, is an oral, once-daily compound belonging to a new drug class, sodium glucose co-transporter (SGLT-2) inhibitors (*Br J Cardiol* doi: 10.5837/bjc.2012.005).

## Yoghurt also reduces diabetes risk...

High consumption of yoghurt compared to no consumption can reduce the risk of new-onset type 2 diabetes by 28% according to a study published in *Diabetologia* recently (doi: 10.1007/s00125-014-3176-1).

## ...and increasing steps by 2,000 a day

A large international study of people with impaired glucose tolerance (IGT) has found that for every additional 2,000 steps taken a day over one year – roughly equivalent to 20 minutes a day of moderately-paced walking – reduces risk of cardiovascular events by 8%.

Published in *The Lancet* (doi: 10.1016/S0140-6736(13)62061-9), data on 9,306 adults from 40 countries with IGT and cardiovascular disease or at least one cardiovascular risk factor were taken from the NAVIGATOR trial. All participants received a lifestyle modification programme aimed at reducing body weight and dietary fat intake while increasing physical activity to 150 minutes a week.

Both levels of walking activity at the start of the study and change in walking activity over 12 months had a graded inverse association with subsequent risk of cardiovascular disease. Specifically, for every 2,000 steps per day difference in walking activity at the start of the study there was a 10% difference in the risk of cardiovascular disease in subsequent years.

## New treatments for PH

Two new treatments for pulmonary hypertension (PH), which will help improve the quality of life in these patients, have been recommended by the European authorities.

Macitentan (Opsumit®, Actelion) has been granted European Marketing Authorisation for the long-term treatment of pulmonary arterial hypertension (PAH). Macitentan, a novel dual endothelin receptor antagonist (ERA), is indicated as a monotherapy or in combination, for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III. This follows results from the SERAPHIN trial which demonstrated macitentan's long-term efficacy in a PAH population of 742 patients. Macitentan 10 mg resulted in a 45% risk reduction of the composite morbidity-mortality end point when compared to placebo.

Riociguat (Bayer) has been recommended for approval by the European Committee for Medicinal Products for both chronic thromboembolic PH (CTEPH) and PAH. Riociguat is the first of a novel class of drugs, the soluble guanylate cyclase-stimulators. The CHEST-1 and PATENT-1 studies showed it improves exercise capacity in both these groups of patients and it is the first agent to demonstrate efficacy in two life-threatening PH indications.

The final decision of the European Commission is expected in the first half of 2014.

## New class of cholesterol-lowering drugs

A new class of cholesterol-lowering drugs that target the production of the cholesterol regulator PCSK9 has been found to reduce low-density lipoprotein (LDL) cholesterol by an average of 40% and up to 57% in phase 1 studies in healthy volunteers.

The drug – ALN-PCS – a small interfering ribonucleic acid (siRNA) works by blocking PCSK9, a protein that destroys LDL receptors that normally clear LDL cholesterol from the blood. Mutations can result in PCSK9 concentrations rising which lead to high LDL cholesterol levels. If successfully developed, the drug could be an alternative for the one in five people who are resistant to statins, or further reduce cholesterol in people in whom current first-line treatments are not enough.

The study is published in *The Lancet* (doi: 10.1016/S0140-6736(13)61914-5).

## EU approval for first leadless pacemaker and...

The first leadless pacemaker (Nanostim™, St Jude Medical) has been given a CE Mark in Europe. The pacemaker is 10% smaller in size than conventional pacemakers and it eliminates the need for surgical pockets. This means it is more comfortable for patients, there is no lump or scar at the implant site, and complications that can lead to device-related infections and lead failure, are reduced.

## ...transcatheter heart valve

The Sapien ST™ (Edwards) transcatheter heart valve has also received the CE Mark in Europe for valve-in-valve procedures. This offers a minimally invasive treatment option for patients whose surgical mitral or aortic valves require replacement and who are at very high risk for surgery; patients who may have gone untreated due to the challenging surgery required.