# Meeting report

## **43rd Annual Meeting of the European Association for the Study of Diabetes**

17-21 September 2007, Amsterdam, The Netherlands

### **IDF recommends tighter blood glucose control after meals**

New guidelines launched by the IDF at the 2007 EASD conference emphasise that people with diabetes should have their blood glucose levels closely monitored after meals in order to optimise diabetes control and reduce the risk of complications, particularly cardiovascular disease.

The new guidelines recommend that people with diabetes try to keep postprandial blood glucose levels below 7.8 mmol/l for the 2 hours following a meal. This 2-hour time frame for measuring blood glucose conforms to guidelines published by most of the leading diabetes organisations and medical associations.

The IDF goes on to suggest that self-monitoring of blood glucose is the most practical method for measuring postprandial glucose levels and allows people with diabetes to obtain 'real-time' information. This allows the individual and their healthcare providers to make timely adjustments to their treatment regimens to achieve and maintain blood glucose targets.

The guidelines also offer a series of recommendations on optimising glycaemic control, including treatment strategies and non-pharmocological therapies. Professor Antonio Ceriello, Chair of the Guidelines writing group, added that physical activity, healthy eating and weight control 'remain the cornerstone of effective diabetes management and not only reduce postmeal glucose levels, but also improve blood pressure and cholesterol levels.'

### Interim 1-year data from the 4-T trial investigating effect of insulin regimens on HbA<sub>1c</sub>

Results from a UK study by the University of Oxford have shown that three different types of insulin analogues improve glucose control when added to oral therapy. The regimens were as follows: biphasic insulin aspart 30 injections BD; mealtime insulin aspart injections TD; and once-daily insulin detemir.

The Treating To Target in Type 2 Diabetes (4-T) trial enrolled people with type 2 diabetes whose glucose control was inadequate despite taking two different OHAs.

Adding these insulin analogues to existing dual oral therapy of metformin plus a sulphonylurea lowered HbA<sub>1c</sub> within 3 months and sustained these reductions to give a drop at 1 year of 1.3 % with biphasic, 1.4 % with mealtime and 0.8 % with basal insulin. While basal insulin detemir had the smallest decrease in HbA<sub>1c</sub>, it was associated with less frequent episodes of hypoglycaemia and less weight gain.

The final 2 years of the 4-T study are designed to determine how often a second insulin needs to be added to a simple regimen and whether or not glucose targets can be met when two types of insulin are used together.

#### New insulin pen for children is launched in UK

On 19 September at the EASD conference, Eli Lilly & Company launched a new reusable insulin pen, HumaPen Luxura HD, that doses in halfunit increments from 1 to 30 units of insulin.

To further support children with diabetes and their caregivers, a series of patient information packs and education materials featuring the cartoon character Hu-Mee the Frog are supplied with the pen. Commenting on the announcement, Simon O'Neill, Director of Care, Information and Advocacy Services at Diabetes UK, said: 'For a child with type 1 diabetes, their journey with the condition can feel overwhelming and difficult to manage. We welcome the development of any medicines or supporting materials that can make this passage a little easier for them and their families.'

### Insulin for Life coordinates global medical donation programme

Insulin for Life (IFL) Global collects diabetes supplies (including test strips and insulin) donated to its centres in the UK, Austria, Germany and the US and supplies them in response to specific requests from recognised organisations from countries in need or areas that have suffered a recent major disaster, such as a hurricane or tsunami.

In many countries, insulin can cost the user more than 50 % of their annual income. IFL Global donates the equivalent of 200 000 ml of insulin per year.

## Eight-year data for Exubera demonstrate long-term safety

An 8-year extension study involving Exubera (human insulin [rDNA origin]) suggested that the inhaled agent was well tolerated and effective in the long term.

The trial included people with type 1 or type 2 diabetes who had completed any of the three 3-month randomised phase 3 Exubera clinical trials with or without Exubera use. In total, 173 individuals were enrolled in the Exubera group, and 44 in the comparator group. Fifty-two remained in the study for 8 years.

After 8 years, the study found that the average yearly reductions in lung function were similar in people who used Exubera and those who did not (yearly rate of decline: Exubera: -49 ml; comparator: -71 ml).

Also demonstrated was

Exubera's long-term efficacy. Glycaemic control as measured by  $HbA_{1c}$  was 8.5% at the beginning of the study in those using Exubera. This decreased after 3 months of therapy and the lower  $HbA_{1c}$  was maintained over the 8 years. The final average  $HbA_{1c}$  was 7.9%.

Hypoglycaemia was the most common adverse event in the Exubera group; however, the rate of hypoglycaemic events decreased from 2.9 episodes per month at 1 month to 1.7 episodes per month after 8 years. The three most common respiratory adverse events were respiratory tract infections (67.6 %), cough (41.6 %) and sore throat (38.2 %). The study did not have a control group beyond 2 years, but no events occurred with consistency.

### New study results support cardioprotective effects of pioglitazone

Two studies presented at the 2007 EASD Annual Meeting provided new data for CV event risk reduction in people with type 2 diabetes treated with the TZD pioglitazone.

Xu et al (Abstract 1257) demonstrated in a retrospective, claims-based study that pioglitazone as mono or combination therapy can reduce the risks of stroke and MI in type 2 diabetes (relative risk versus non-TZD therapy of 0.800 [95 % CI: 0.716–0.893] and 0.621 [95 % CI: 0.503–0.766], respectively).

Three-month data of the 6-month trial by McCall et al (Abstract 0865) suggested that starting doses of pioglitazone (30 mg) and rosiglitazone (5 mg) differed

significantly in terms of their impacts on triglycerides, HDL-cholesterol and HbA1c in favour of pioglitazone (P<0.001, P<0.001, and P=0.017, respectively). 'A likely explanation for the different effects on heart attack and strokes between the two agents could be the favourable effect of pioglitazone in increasing HDL-c without adverse effects on LDL-c,' said John Betteridge, Professor of Endocrinology and Metabolism at University College, London.

These findings correlate with those from Lincoff et al's recent meta-analysis that demonstrated an 18 % risk reduction for heart attack, stroke or death in people with type 2 diabetes.

### Industry update

### NICE confirms cost– effectiveness of Ezetrol

On 17 November 2007, NICE issued a Final Appraisal Determination recommending that ezetimibe (Ezetrol, MSD and Schering-Plough, UK), co-administered with a statin, is a cost-effective option for individuals whose serum total cholesterol or LDL-c is not appropriately controlled on the initial statin, which has been titrated appropriately, and who are being considered for an alternative statin.

NICE drew this conclusion after reviewing a meta-analysis that demonstrated that the absolute further reduction in LDL-c attributed to ezetimibe was approximately 22%. This compares with switching statins, which only yields an additional LDL-c reduction of 8%.

NICE also advocates the use of ezetimibe as monotherapy when statins are contraindicated, or if a person is intolerant of statins. In the appraisal, statin intolerance is defined as the presence of clinically significant adverse events that are considered to represent an unacceptable risk or may result in compromising compliance.

### **DPP-4 inhibitor vildagliptin granted European license**

Vildagliptin (Galvus, Novartis) has been granted EU approval for use in treating people with type 2 diabetes in combination with the most common OHAs – metformin, TZDs or SUs.

Vildagliptin is a DPP-4 inhibitor and reduces blood glucose by targeting the dysfunction in the pancreatic islets that cause high blood glucose levels in people with type 2 diabetes.

The reduction in blood glucose associated with vildagliptin in combination with other OHAs is observed across a range of people with type 2 diabetes, including those from varied ethnic groups, the elderly and those with uncontrolled blood glucose levels.

In clinical trials, vildagliptin demonstrated an overall incidence of side effects similar to placebo. The most common side effects observed with vildagliptin use were stuffy nose, headaches, dizziness and upper respiratory tract infection.

The approval applies in all 27 countries of the EU as well as in Norway and Iceland.