

Latest data demonstrate sustained results of Bydureon[®] (exenatide once-weekly) treatment over six years with a second, retrospective study showing a higher likelihood of adherence with exenatide once-weekly vs. other GLP-1 therapies in type 2 diabetes patients

- **Data presented today at the 74th Scientific Sessions of the American Diabetes Association (ADA) demonstrate exenatide once-weekly treatment sustaining reductions in HbA1c from baseline and secondary weight loss benefit over six years¹**
- **A separate retrospective study also showed a significantly higher likelihood of patient adherence following initiation of exenatide once-weekly compared to liraglutide once-daily and exenatide twice-daily²**

Luton, Bedfordshire, UK, Monday 16 June, 2014 – Data presented today at the 74th Scientific Sessions of the American Diabetes Association (ADA), show that Bydureon[®] (exenatide once-weekly) treatment was associated with clinically significant improvements in glycaemic control and weight loss that were sustained over six years in patients who continued therapy. This latest data from the extension of the DURATION-1 trial represents the longest assessment of a glucagon-like peptide-1 (GLP-1) receptor agonist for the treatment of type 2 diabetes to-date.¹

The data presented at the ADA meeting showed that for the 127 patients who completed exenatide once-weekly treatment over six years, HbA1c levels improved significantly from baseline (LS mean -1.6% [95% CI -1.9, -1.4]),¹ with almost half (45%) still achieving HbA1c < 7.0% and almost one-third (32%) achieving HbA1c ≤ 6.5%.¹ In addition, an average weight reduction of -4.3kg from baseline was observed in patients who completed six years of treatment, as well as a reduction in fasting plasma glucose (FPG) of 29mg/dL from baseline.¹

Debbie Hicks, Nurse Consultant – Diabetes at Enfield Community Services, Barnet, Enfield and Haringey Mental Health Trust, commented “The results from the DURATION-1 extension study are reassuring as they demonstrate the durability of exenatide once-weekly treatment over six years, which is an unprecedented trial length for a GLP-1 receptor agonist study to-date. In my clinical practice, it is very important that I can offer a treatment to my type 2 diabetes patients that I can be confident will not lose its efficacy over a short period of time. Generally, my patients are also more likely to adhere to a once weekly medication than one given more frequently. Today’s results provide very encouraging, long term data around the effective use of exenatide once-weekly for sustained glycaemic control as well as providing a secondary weight loss benefit.”

The original 30-week randomised, open-label DURATION-1 study (n=295) compared exenatide once-weekly with exenatide twice-daily in type 2 diabetes patients on oral glucose-lowering therapies. The results showed treatment with exenatide once-weekly was associated with a greater reduction in HbA1c from baseline than those receiving exenatide twice-daily (-1.9% vs. -1.5%; P=0.002), with similar weight loss between groups.¹ In the open-ended extension of DURATION-1, all patients received exenatide once-weekly (those on exenatide twice-daily were switched to exenatide once-weekly treatment). The results showed that exenatide once-weekly was associated with significant improvements from baseline in glycaemic control and fasting plasma glucose at each annual timepoint, including at six years.¹ There were also improvements from baseline in weight at most annual timepoints, including at six years.¹

There were no unexpected safety findings from the DURATION-1 extension. Notably, the rate of some adverse events, such as nausea, and pruritus (itching) and erythema (redness of the skin) at the injection site, diminished over time.¹ No cases of major hypoglycaemia were reported and cases of minor hypoglycaemia were largely dependent on background therapy with most events occurring with concomitant sulfonylurea use.¹

In a separate retrospective study presented at ADA, data showed that GLP-1-naïve patients with type 2 diabetes were significantly more likely to adhere following initiation of exenatide once-weekly, compared to liraglutide once-daily and exenatide twice-daily.² In the retrospective cohort study in the United States, prescription claims data were used to compare proportion of days covered (PDC) as a measure of adherence to the different regimens.² During the six months after GLP-1 initiation, 49% of patients in the exenatide once-weekly group (n=4,041) had a PDC of $\geq 80\%$, compared to 44% in the liraglutide once-daily group (n=14,211, p<0.001) and 30% in the exenatide twice daily group (n=4,586, p<0.001).²

“The DURATION-1 study showed that treatment with Bydureon can help patients reach HbA1c levels that are in line with NICE guidelines and that they can maintain these results through six years of treatment,” noted Lisa Anson, President, AstraZeneca UK and Ireland. “Bydureon is the only GLP-1 to offer this level of efficacy combined with a secondary benefit of weight loss, in a single, once-weekly injection.”

These data follow shortly after positive long-term findings from a three-year head-to-head study of exenatide once-weekly and insulin glargine (DURATION-3), published in the June 2014 issue of the *Lancet Diabetes and Endocrinology*. The results of this study indicate that exenatide once-weekly can achieve improved glycaemic control, weight loss and lower incidence of hypoglycaemia, compared to

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treatment with insulin glargine, in addition to significant improvements in several measures of weight-related quality of life.³

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For further information, please contact:

Elisa Agate, AstraZeneca, 01582 836307 / 07780 493687, elisa.agate@astrazeneca.com

Jessica Pacey, Packer Forbes Communications, 020 7036 8550, jessica@packerforbes.com

Lucia Giffard, Packer Forbes Communications, 020 7036 8550, lucia@packerforbes.com

Notes for editors

About Bydureon[®] (exenatide once-weekly)*

Exenatide once-weekly is indicated for treatment of type 2 diabetes mellitus in combination with:⁴

- Metformin
- Sulphonylurea
- Thiazolidinedione
- Metformin and sulphonylurea
- Metformin and thiazolidinedione

In adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

For further information about exenatide once-weekly, including the full therapeutic indication, adverse reactions, precautions, contraindications, and method of use, see the Summary of Product Characteristics (SmPC) available at:

<http://www.medicines.org.uk/emc/medicine/24665/SPC/BYDUREON+2+mg+powder+and+solvent+for+prolonged-release+suspension+for+injection/>

*Exenatide is not indicated for weight loss. Rapid weight loss at a rate of >1.5 kg per week has been reported in patients treated with exenatide. Weight loss of this rate may have harmful consequences.⁴

About GLP-1 receptor agonists

- GLP-1 receptor agonists are a class of injectable anti-hyperglycaemic agents used in the treatment of type 2 diabetes and they mimic several of the actions of the naturally occurring hormone GLP-1, including lowering blood glucose levels.⁴

- GLP-1 receptor agonists, such as exenatide once-weekly, work by stimulating insulin secretion from the pancreatic beta cells on a glucose-dependent basis, suppressing glucagon secretions, decreasing appetite which can lead to reduced food intake and the slowing of gastric emptying, reducing the rate at which glucose from meals appears in the blood.⁴

About diabetes

- An estimated 2.88 million people in the UK are living with type 2 diabetes and a further 765,000 people are thought to have undiagnosed type 2 diabetes.^{5,6} * Obesity is the most potent risk factor for type 2 diabetes, accounting for 80-85% of the overall risk of developing type 2 diabetes.⁶ (See type 2 diabetes factsheet for further information)

*Calculations based on 90% of diabetes population in UK having type 2 diabetes.^{5,6}

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit www.astrazeneca.com.

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