



# Company Announcement

26 January 2010

## Novo Nordisk receives US approval for Victoza<sup>®</sup> (liraglutide) for the treatment of type 2 diabetes

Novo Nordisk announced today that the US Food and Drug Administration (FDA) has granted marketing authorisation for Victoza<sup>®</sup> for the treatment of type 2 diabetes in adults.

Victoza<sup>®</sup> is the brand name approved in the US and Europe for liraglutide, the first once-daily human Glucagon-Like Peptide-1 (GLP-1) analogue developed for the treatment of type 2 diabetes. In the US, Victoza<sup>®</sup> is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. This provides for Victoza<sup>®</sup> to be used in monotherapy, as second-line treatment and in combination with commonly prescribed oral medications for diabetes.

"The US approval of Victoza<sup>®</sup> represents a major advancement in the treatment of type 2 diabetes and is an important milestone for Novo Nordisk that follows the recent approval in Japan and the ongoing successful launch in Europe." says Lars Rebien Sørensen, president and CEO. "We are convinced that Victoza<sup>®</sup> will prove to be a valuable treatment option for people with type 2 diabetes in the US. The ability of Victoza<sup>®</sup> to substantially improve glucose control with a low risk of hypoglycaemia creates an opportunity for more patients with type 2 diabetes to achieve their individual treatment goals."

Novo Nordisk expects to introduce Victoza<sup>®</sup> in the US market within weeks.

### **Clinical results: LEAD<sup>™</sup> (Liraglutide Effect and Action in Diabetes)**

The Victoza<sup>®</sup> phase 3 clinical trial programme, entitled LEAD<sup>™</sup>, which formed the basis of the regulatory submission, is comprised of randomised, controlled, double-blinded studies comparing Victoza<sup>®</sup> to commonly prescribed treatments. These multinational trials evaluated Victoza<sup>®</sup> in monotherapy as well as in combination with one or two oral antidiabetic medications and showed better or

equivalent lowering of blood glucose than active comparators such as sulphonylureas and thiazolidinediones.

Unlike many other diabetes medications, Victoza<sup>®</sup> is not associated with weight gain. For patients with type 2 diabetes, clinical trial data demonstrate a reduction in body weight in the LEAD<sup>™</sup> programme. Body weight was a secondary endpoint in the clinical development trials.

The most common adverse events reported during the clinical development programme in patients treated with Victoza<sup>®</sup> were associated with the gastrointestinal system. Gastrointestinal adverse events, including nausea, vomiting and diarrhoea were reported most frequently in the early part of the treatment period with Victoza<sup>®</sup> and few patients withdrew due to these adverse events.

### **Important safety information**

The US prescribing information includes a boxed warning for the risk of thyroid c-cell tumours. In preclinical testing, Victoza<sup>®</sup> caused thyroid c-cell tumours in rodents. In clinical trials there were no reported cases of medullary thyroid carcinoma (MTC) in patients treated with Victoza<sup>®</sup>, but human relevance of the rodent findings could not be ruled out by clinical or non-clinical studies. Victoza<sup>®</sup> is contraindicated in patients with a personal or family history of MTC or Multiple Endocrine Neoplasia syndrome type 2.

The marketing authorisation further includes a risk evaluation and mitigation strategy (REMS) programme comprised of a Medication Guide to patients and a Communication Plan directed at healthcare providers – both informing about the risk of pancreatitis and the potential risk of MTC.

### **Conference call**

On 26 January 2010 at 08:00 am CET, corresponding to 02:00 am EST, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of [novonordisk.com](http://novonordisk.com). Presentation material for the conference call will be made available approximately one hour before on the same page, and a replay of the conference call will be available approximately two hours after its conclusion.

### **About Victoza<sup>®</sup>**

Once-daily Victoza<sup>®</sup> is the first human Glucagon-Like Peptide-1 (GLP-1) analogue developed for the treatment of type 2 diabetes. Victoza<sup>®</sup> works by stimulating the release of insulin from the pancreatic beta cells only when blood sugar levels are high. Clinical trial data demonstrate a reduction in body weight. Victoza<sup>®</sup> is broken down naturally in the body and does not depend upon renal excretion.

In Europe, Novo Nordisk received marketing authorisation for Victoza<sup>®</sup> on 30 June and Victoza<sup>®</sup> has subsequently been launched in the UK, Germany, Denmark, Norway and Ireland. In Japan, Novo Nordisk received marketing

authorisation for Victoza® on 20 January 2010. A regulatory decision is pending in China where a New Drug Application was submitted in August 2009.

*Novo Nordisk is a healthcare company and a world leader in diabetes care. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. With headquarters in Denmark, Novo Nordisk employs more than 29,000 employees in 81 countries, and markets its products in 179 countries. Novo Nordisk's B shares are listed on the stock exchanges in Copenhagen and London. Its ADRs are listed on the New York Stock Exchange under the symbol 'NVO'. For more information, visit [novonordisk.com](http://novonordisk.com).*

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