



# Press Release

For Immediate Release

## Data analysis reinforces the safety profile of Levemir®

**Princeton, N.J. (Oct. 20, 2009)** – A meta-analysis of clinical data published today in *Diabetologia*, the medical journal for the European Association for the Study of Diabetes (EASD), demonstrated that the Novo Nordisk long-acting insulin Levemir® (insulin detemir [rDNA origin] injection) was not associated with any increase in the incidence of cancer when compared to human insulin<sup>1,2</sup>.

The analysis conducted by Novo Nordisk assessed the relative risk of a cancer diagnosis during clinical treatment with Levemir®. It included approximately 9,000 patients (approximately 5,200 taking Levemir®) in 21 randomized controlled trials and compared the incidence of cancer in patients treated with Levemir® with that of patients treated with either human insulin (NPH insulin) or insulin glargine.

The data revealed that treatment with Levemir® was associated with a statistically significantly lower incidence of cancer than with NPH insulin treatment (0.36 events per 100 patient years in the Levemir® group vs. 0.92 events in the NPH insulin group;  $p < 0.05$ ).

The incidence of cancer during Levemir® treatment was also lower than that seen during treatment with insulin glargine, but this difference was not statistically significant (0.87 events per 100 patient years in the Levemir® group vs. 1.27 events in the insulin glargine group;  $p > 0.05$ )<sup>3</sup>.

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<sup>1</sup> DIABETOLOGIA ONLINE: Dejgaard A et al. No increased risk of malignancies in patients treated with insulin detemir – a meta-analysis.

<sup>2</sup> Novo Nordisk data on file, presented at the EASD on 1 October 2009, to be published

<sup>3</sup> A meta-analysis is a systematic method that uses statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study. Source: National Information Center on Health Services Research and Health Care Technology (NICHSR). <http://www.nlm.nih.gov/nichsr/hta101/ta101014.html>

“We have designed Levemir with all aspects of safety for the patient in mind and these data are in line with what we would expect” said Dr. Alan Moses, Novo Nordisk Vice President and Chief Medical Officer. “Physicians, health care providers and patients can continue to feel confident in using Levemir® to effectively treat type 1 and type 2 diabetes.”

The analysis was performed in response to the *Diabetologia* June publication of four registry studies<sup>4</sup>. Those studies, while inconclusive due to methodological limitations, suggested a potential link between another long-acting insulin analog, insulin glargine, and cancer. As a basis for such a possible link, an accompanying editorial explained that certain insulin analogs have a structure making them more likely to bind to the IGF-1 receptor which is known to be involved in promoting tumor growth<sup>5</sup>.

The full text of the manuscript can be found online at <http://www.diabetologia-journal.org>.

### **About Levemir®**

Levemir® (insulin detemir [rDNA origin] injection) is a man-made long-acting insulin that is used to control high blood sugar in adults and children with diabetes mellitus.

### **Important Safety Information:**

Do not take Levemir® if your blood sugar is too low (hypoglycemia) or if you are allergic to anything in Levemir®. If you take too much Levemir® your blood sugar may fall too low.

Check your blood sugar levels. Ask your health care provider what your blood sugars should be and when you should check your blood sugar levels. Alcohol, including beer and wine, may affect your blood sugar when you take Levemir®.

Do not change the type of insulin you use unless told to do so by your health care provider. The amount of insulin you take as well as the best time for you to take your insulin may need to change if you take a different type of insulin.

Never mix Levemir® with other insulin products or use in an insulin pump.

Needles and Levemir® FlexPen® must not be shared.

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<sup>4</sup> [www.diabetologia-journal.org](http://www.diabetologia-journal.org)

<sup>5</sup> Kurtzhals P, Schäffer L, Sørensen A, Kristensen C, Jonassen I, Schmid C, Trüb T (2000): Correlations of receptor binding and metabolic and mitogenic potencies of insulin analogs designed for clinical use. *Diabetes* 49: 999-10055.

Tell your health care provider about all medicines you take and all of your medical conditions, including if you are pregnant or breastfeeding. Your Levemir® dose may change if you take other medicines.

The most common side effect of Levemir® is low blood sugar (hypoglycemia). Other possible side effects include reactions at the injection site (like redness, swelling and itching), and allergic reactions. Get medical help right away if you experience signs of serious allergic reaction such as body rash, trouble with your breathing, fast heartbeat, or sweating. Ask your doctor or pharmacist for further information.

For full prescribing information, visit <http://www.levemir-us.com>.

Levemir® is a registered trademark of Novo Nordisk A/S.

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Novo Nordisk is a healthcare company with an 86-year history of innovation and achievement in diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems. In addition to diabetes care, Novo Nordisk has a leading position within areas such as hemostasis management, growth hormone therapy, and hormone therapy for women. Novo Nordisk's business is driven by the Triple Bottom Line: a commitment to economic success, environmental soundness, and social responsibility to employees and customers. With headquarters in Denmark, Novo Nordisk employs more than 26,000 employees in 80 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 global information, visit [novonordisk.com](http://novonordisk.com); for United States information, visit [www.novonordisk-us.com](http://www.novonordisk-us.com).

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