



# Press release

FOR IMMEDIATE RELEASE

## FDA Approves NovoLog<sup>®</sup> for Use in Insulin Pumps by Children and Adolescents

### Data Demonstrates Efficacy and Safety for Patients aged 4 to 18

**Princeton, NJ (March 17, 2008)** – Novo Nordisk today announced that the U.S. Food and Drug Administration has approved NovoLog<sup>®</sup> (insulin aspart [rDNA origin] injection) for continuous subcutaneous insulin infusion (CSII) by external insulin pump in pediatric patients between the ages of 4 and 18 years.<sup>1</sup> NovoLog<sup>®</sup> is the first and only insulin analog approved for this use.

Data from a trial published in the February issue of *Diabetes Care* in support of this approval demonstrated that compared to insulin lispro CSII, NovoLog<sup>®</sup> CSII achieved similar levels of glycemic control and safety. Results came from a 16-week, open-label, multi-center, parallel group study of 298 patients (aspart, n= 198; lispro, n = 100) (aged 4-18 years; type 1 diabetes duration  $\geq 1$  year; CSII therapy treatment  $\geq 3$  months; A1C $\leq 10.0\%$  at screening).<sup>2</sup>

“The approval of NovoLog<sup>®</sup> in insulin pumps for the pediatric population highlights the safety and efficacy of NovoLog<sup>®</sup> and underscores Novo Nordisk’s commitment to providing treatments that benefit this sometimes overlooked segment of the diabetes population,” said Alan C. Moses, M.D., vice president, chief medical officer worldwide.

#### About the Study

Patients in the study were randomized 2:1 to NovoLog<sup>®</sup> CSII or insulin lispro CSII via external pump with changes in reservoir, infusion set and infusion site at least once every 48 hours. Patients were stratified by age (3-5, 6-11 and 12-18 years) prior to randomization to ensure

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that both treatment groups had a similar proportion of young children, children and adolescents.<sup>2</sup> By study end:

- Both treatments resulted in comparable changes in baseline in A1C. Nearly 60% of NovoLog<sup>®</sup> patients (versus 43.8% of insulin lispro patients) achieved age-specific A1C goals, defined by the American Diabetes Association as <8.5% for subjects aged <6 years and <8% for subjects aged 6-18 years<sup>2</sup>
- Weight-adjusted mean daily dose of NovoLog<sup>®</sup> (0.86 unit/kg) was significantly less than that of insulin lispro (0.94 unit/kg) ( $P=0.018$ )<sup>2</sup>
- Rates of hypoglycemia and numbers and types of adverse events were similar between both treatment groups<sup>2</sup>

“NovoLog<sup>®</sup> CSII was shown to be safe and tolerable in pediatric subjects between the ages of 4 and 18 years old,” said Dr. Stuart A. Weinzimer, lead study author. “The results of this study confirm that NovoLog<sup>®</sup> CSII therapy is efficacious in appropriately selected children and adolescents.”

### **About NovoLog<sup>®</sup>**

NovoLog<sup>®</sup> is an insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus. NovoLog<sup>®</sup> has a more rapid onset and shorter duration of action than regular human insulin. An injection of NovoLog<sup>®</sup> should be immediately followed by a meal. Because of the short duration of action of NovoLog<sup>®</sup>, a longer-acting insulin should also be used in patients with type 1 diabetes and may also be needed in patients with type 2 diabetes. NovoLog<sup>®</sup> is contraindicated during episodes of hypoglycemia and in patients hypersensitive to NovoLog<sup>®</sup> or one of its excipients. Hypoglycemia is the most common adverse effect of insulin therapy, including, NovoLog<sup>®</sup>. Adverse reactions observed with NovoLog include hypoglycemia, allergic reactions, local injection site reactions, lipodystrophy, rash and pruritis.

Any change of insulin dose should be made cautiously and only under medical supervision.

Prescribing information for NovoLog<sup>®</sup> is available by contacting Novo Nordisk or by visiting [novonordisk-us.com](http://novonordisk-us.com).

### **About Novo Nordisk**

Novo Nordisk is a healthcare company with an 85-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 [novonordisk-us.com](http://novonordisk-us.com).

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<sup>1</sup> NovoLog prescribing information. Available at [http://www.novolog.com/NovoLog\\_Prescribing\\_Info.pdf](http://www.novolog.com/NovoLog_Prescribing_Info.pdf). Accessed on March 17, 2008.

<sup>2</sup> Weinzimer, Stuart A. MD, et al. A Randomized Trial Comparing Continuous Subcutaneous Insulin Infusion of Insulin Aspart Versus Insulin Lispro in Children and Adolescents with Type 1 Diabetes. *Diabetes Care*. 2008;31(2): 210-214.