



Press Release, June 28, 2011

## **TrialNet presents results from a study with Diamyd®**

*Diamyd Medical AB reports that the results of a study with the Company's antigen-based diabetes therapy Diamyd®, conducted by the research consortium Type 1 Diabetes TrialNet did not show a statistically significant effect of the study drug.*

The American research consortium Type 1 Diabetes TrialNet presented their results of a Phase II study with the antigen-based diabetes therapy Diamyd® yesterday, June 27, at the American Diabetes Association 71<sup>st</sup> Scientific Sessions (ADA) in San Diego, California, USA, after the closing of the stock market. At the same time a research article about the study was published on the homepage of the medical journal *The Lancet* entitled "Antigen-based therapy with glutamic acid decarboxylase (GAD) vaccine in patients with recent-onset type 1 diabetes: a randomised double-blind trial". The study did not reach the primary efficacy endpoint of preserving endogenous insulin production, as measured by meal-stimulated C-peptide, in patients treated with Diamyd® compared to placebo. There was no statistically significant difference in hemoglobin A1c (HbA1c) or mean daily insulin dose between the groups receiving Diamyd® and the placebo treated group.

The Phase II study conducted by Type 1 Diabetes TrialNet is a multicenter, randomized, double-blind study that recruited 145 patients, 3 to 45 years old, in the United States and Canada. The patients, diagnosed with type 1 diabetes within three months of entering the study, were divided into three equal groups of which one group received three injections of Diamyd® (day 1, 30 and 90), one group received two injections of Diamyd® and one injection of placebo, and one group received three injections of placebo. All of the patients had some endogenous insulin production left and were GAD-antibody positive at entering the study. The patients have been followed for 12 months and will be followed for another 12 months. Diamyd® was well tolerated, as demonstrated by a similar number of adverse events reported in the groups treated with Diamyd® and in the placebo group.

"The outcome in this North American study was unfortunately not better than in our larger European Phase III study," says Peter Zerhouni, Acting President and CEO of Diamyd. "However, TrialNet concluded in its presentation that Diamyd® and the active substance GAD65 may have an effect when given earlier in the disease process to prevent type 1 diabetes, in a different treatment regimen, or in combination with other drugs."

On May 9, 2011, Diamyd Medical announced that a European Phase III study with Diamyd® did not meet the primary efficacy endpoint of preserving beta cell function at 15 months, as measured by meal-stimulated C-peptide, although a small positive effect was seen. Furthermore, Diamyd® was well tolerated as demonstrated by a similar number of adverse events in the Diamyd® treated groups compared to the placebo treated group. The follow-up period of the European Phase III study was closed on June 1, 2011. Detailed results of the European study will be presented later today, June 28, at the diabetes conference ADA in San Diego.

On June 23, Diamyd announced that the Company decided to initiate closure of the parallel US Phase III study DiaPrevent, based on a blinded analysis of efficacy data collected to date in the study, and the data from the European Phase III study.

An externally funded and researcher-initiated Phase II study with Diamyd® is being conducted, aiming to prevent type 1 diabetes in children at high risk of developing the disease. That study is not affected by the findings in the other studies with Diamyd®.

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**About the diabetes therapy Diamyd®**

Diamyd® is an antigen-based diabetes therapy under development. The active substance in Diamyd® is the human protein GAD65 (Glutamic acid decarboxylase isoform 65 kDa). The development has been ongoing since 1994 when Diamyd Medical signed an exclusive license to patents and patent applications related to the GAD65-molecule with the University of California, Los Angeles (UCLA).

The purpose of the therapy is to prevent, delay, or stop the autoimmune attack on beta cells in type 1 diabetes and other forms of autoimmune diabetes, thereby preserving the body's capacity to regulate blood sugar. This reduces the risk for both acute and long term diabetes complications significantly. A Phase II study of 70 children and adolescents with type 1 diabetes published in The New England Journal of Medicine in 2008 showed that Diamyd® significantly slowed the progression of the disease in subjects treated within 18 months of being diagnosed with type 1 diabetes.

**About Diamyd Medical**

Diamyd Medical is a Swedish pharmaceutical company focusing on the development of pharmaceuticals for the treatment of autoimmune diabetes and pain. The Diabetes business area consists of the antigen-based drug candidate Diamyd® for the treatment and prevention of autoimmune diabetes. The Pain business area consists of development projects that use the Company's proprietary NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs directly to the nervous system to treat chronic pain. A Phase II study of the candidate drug NP2 Enkephalin for cancer pain is ongoing in the US.

Diamyd Medical has offices in Sweden and in the US. Shares are listed on Nasdaq OMX in Stockholm (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY) administered by the Pink OTC Markets and the Bank of New York Mellon (PAL). Further information is available on the company's website: [www.diamyd.com](http://www.diamyd.com).

*This information is disclosed in accordance with the Swedish Securities Markets Act, the Swedish Financial Instruments Trading Act, or the requirements stated in the listing agreements.*

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