



Press Release, August 27, 2009

Diamyd to include children and accelerate patient recruitment in US Phase III study with the Diamyd[®] diabetes vaccine

Diamyd Medical reported today that from September 1, children from 10 years of age with type 1 diabetes will be included in the company's US Phase III study of the Diamyd[®] diabetes vaccine. The company is also trebling the number of clinics and is investing in expanded recruitment activities in the US.

Diamyd Medical's Phase III study of the Diamyd[®] diabetes vaccine in the US has so far only been open to patients with type 1 diabetes aged between 16 and 20 years. From September 1, 2009, the study will also be open to children in the age range 10 to 15 years. Following the FDA's decision in June to reduce the lower age limit from 16 to 10 years, the company has concentrated on contacting, visiting and applying for ethical approval for pediatric diabetes clinics throughout the US, and will now begin recruiting younger children. The company will retain 13 of the existing clinics and is negotiating with around 30 new pediatric diabetes clinics in an effort to gradually increase the number of participating clinics to 40.

Diamyd previously announced the evaluation of a consolidation of the company's two Phase III studies. On the advice of the FDA, a decision has now been made to keep the two Phase III studies in Europe and the US separate, but to investigate the practical possibilities of including European patients in the US study, which is conducted under the supervision of the FDA.

"We are now working diligently to recruit patients in the US," says **Elisabeth Lindner**, CEO and President of Diamyd Medical. "Most people who develop type 1 diabetes do so between the ages of 10 and 15 years, which is why the speed of recruitment may increase rapidly in the US study when we include this age group and expand the number of clinics. Our plan is still to obtain market approval for Diamyd[®] in 2012."

Diamyd Medical is conducting a global Phase III program for the Diamyd[®] diabetes vaccine, which includes a total of 640 children and adolescents newly diagnosed with type 1 diabetes. The program comprises one study involving nine European countries and one parallel study in the US. The purpose of the Phase III studies is to confirm and evaluate the ability of the Diamyd[®] vaccine to halt or slow the autoimmune destruction of the body's insulin-producing cells, thereby preserving the body's own ability to produce insulin in people with type 1 diabetes.

In addition to the Phase III program, additional clinical trials with the Diamyd[®] diabetes vaccine are conducted:

- Long-term follow up of the children with type 1 diabetes, who participated in the company's previously reported Phase II study, for the purpose of evaluating the long-term effect of the Diamyd[®] vaccine.
- A Phase II study in the US aiming to preserve the body's own ability to produce insulin, as well as to further investigate the immunological mechanism of action of the Diamyd[®] diabetes vaccine. This study is conducted by TrialNet/National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)/National Institutes of Health (NIH).
- A Phase II study in the US aiming to stimulate regrowth of insulin-producing cells. This study is conducted by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)/National Institutes of Health (NIH).

- A Phase II study in Norway aiming to study the disease process of type 1 diabetes in adults with a high risk of developing the disease.
- A Phase II study in Sweden at Malmö University Hospital, Lund University, aiming to vaccinate children at high risk of developing type 1 diabetes, thereby preventing the disease.

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About Diamyd Medical

Diamyd Medical is a Swedish diabetes company focusing on the development of pharmaceuticals for the treatment of autoimmune diabetes and its complications. The company's most advanced project is the GAD-based drug Diamyd® for type 1 diabetes. Phase III trials for this drug are in progress in both Europe and the US. In addition, the company has initiated clinical studies in the US in the area of chronic pain, using its Nerve Targeting Drug Delivery System (NTDDS). The company has also out-licensed the use of GAD for the treatment of Parkinson's disease. The company currently has three clinical-phase products.

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.

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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