



Press Release, March 4, 2009

## **Pioneering Diamyd® Study to Prevent Childhood Diabetes Approved**

*Diamyd Medical announces today that the Swedish Medical Products Agency has approved a study with the Diamyd® diabetes vaccine in children with high risk to develop type 1 diabetes.*

At Malmö University Hospital, Lund University in Sweden, large screening tests results in a continuous identification of children that are subject to a very high risk of developing type 1 diabetes. By measuring different biomarkers in blood samples, it is possible to determine in an early stage that these children are in the autoimmune disease process that destroys their insulin producing cells. If vaccination with Diamyd® succeeds to intervene in the disease process before too many of the insulin cells are destroyed, the disease will be prevented. The child would then escape diabetes symptoms and would not become dependent on insulin injections for survival, which otherwise is unavoidable.

"We meet with these kids every third month and we know that virtually all of them will present with type 1 diabetes. Many of us pediatricians have been frustrated not to be able to interfere. But now, and I have to admit it feels almost a bit unreal, we may for the first time have a real opportunity to save these children from the disease," says **Helena Elding Larsson**, pediatrician from Malmö and researcher at Lund University in Sweden.

The approved study comprises, under the present approval, up to 50 children from 4 years of age who are known to have a high risk of developing type 1 diabetes. The study will be randomized and placebo controlled.

"To vaccinate children against diabetes has from the outset been one of Diamyd Medical's long term goals," says Elisabeth Lindner, President and CEO of Diamyd Medical. "Type 1 diabetes is a life-long and very serious disease and it is good if we now can prevent it. It would avoid a lot of anxiety, suffering and costs for the children and their families as well as the rest of Society."

Diamyd Medical was founded 15 years ago with the vision to treat and prevent type 1 diabetes with the GAD-molecule, which is the active ingredient in Diamyd®. The vaccine was first studied in adult so called LADA patients, where the Diamyd® vaccine showed it could prevent the need for insulin injections. In a more recent Phase II study, Diamyd® treatment of children and adolescents with type 1 diabetes and a certain remaining endogenous insulin production lead to a clearly improved disease process. The results from this study were published in the New England Journal of Medicine in October 2008. Large Phase III studies in children and adolescents, who recently have been diagnosed with fully developed type 1 diabetes, are now ongoing. Diamyd® treatment has not raised any safety concerns in any study and this strong safety profile has resulted in that Diamyd® now can be studied for prevention of childhood diabetes, according to the Company's original idea.

"To stop the immune attack on the insulin producing cells in type 1 diabetes may be easier the sooner it is done in the disease process", says Professor Åke Lernmark, at Lund University, Sweden. "It is like steering a big boat away from a threatening collision. The sooner the course is changed, the better. A timely change in the course of the disease – no insulin injections – that may be this century's contribution to curing autoimmune diabetes. Last century's contribution? Insulin injections!"

The Diamyd® diabetes vaccine has mainly been developed in Sweden, but with help from leading expertise from all over the world. Diamyd Medical's scientific advisers include Professors Hans Wigzell, Karolinska Institute, Stockholm, Sweden; Lars Klareskog, Karolinska Institute, Stockholm, Sweden; Åke Lernmark,

University of Lund, Sweden; Johnny Ludvigsson, University of Linköping, Sweden; David Leslie, University of London, United Kingdom; Bart Roep, Leiden University, the Netherlands; Jerry Palmer, University of Washington, USA; Mark Atkinson, University of Florida, USA; Daniel Kaufman, University of California, Los Angeles (UCLA), USA; Allan Tobin, UCLA, USA and Joe Glorioso, University of Pittsburgh, USA.

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*Diamyd Medical is a Swedish biopharmaceutical company focusing on development of pharmaceuticals for treatment of autoimmune diabetes and its complications. The company's most advanced project is the GAD-based drug Diamyd® for type 1 diabetes for which Phase III trials are ongoing in both the US and Europe. Furthermore, the company has started clinical studies within 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.*

*Diamyd Medical has offices in Sweden and in the US. The share is quoted on the OMX Stockholm Nordic Exchange (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY) administered by the Pink Sheets and the Bank of New York (PAL). Further information is available on the company's web site: [www.diamyd.com](http://www.diamyd.com).*

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