

# REVOLUTIONARY IMMUNOLOGIC DATA EXPLAINS FUNCTION OF DIAMYD DIABETES VACCINE

Press Release, Stockholm, Sweden, May 3, 2007 – Diamyd Medical AB (www.omxgroup.com ticker: DIAM B; www.otcqx.com ticker DMYDY)

During a presentation made in Linkoping, Sweden at the Sweden-Seattle Diabetes Conference this past week-end, Professor Johnny Ludvigsson, the Principal Investigator in Diamyd's previously reported successful Phase II study in type 1 diabetes, presented potentially scientifically ground-breaking results from a recently completed analysis of the immunological data from the same trial.

The phase II type 1 clinical trial reported positive 15-month clinical results in August 2006. The study was a double blind, randomized and placebo controlled trial that included 70 young type 1 diabetes patients. The patients received two injections, four weeks apart, of either 20  $\mu g$  Diamyd® or placebo. Since this was a double-blinded study, the code containing information on which patients received the Diamyd® vaccine and which patients received placebo was not "unlocked" until 15 months after study initiation.

Vaccination with Diamyd® Counteracts Destruction of Insulin Producing Cells In addition to analysing clinical outcome of Diamyd®, immunological tests were also conducted by the Linkoping team according to international scientific standards. These immunological data was subject to rigorous biostatistical analysis.

At the Conference, Professor Ludvigsson presented startling data based on the immunological analysis from the type 1 diabetes trial. The data illustrates that virtually all patients treated with the Diamyd® therapeutic vaccine had an upregulation of certain beneficial immunological markers in response to the active ingredient in Diamyd®, which according to current opinion may counteract the destruction of insulin producing beta cells by the immune system (the so-called "autoimmune attack"). These immunological markers remained upregulated even 15 months after the first injection, while patients that received placebo showed a downregulation of the same markers over time. Accumulation of scientific evidence has long pointed to GAD65, the active ingredient of Diamyd®, as a possible "immunomodulator" that could prevent the immune system from destroying the insulin producing beta cells.

# **Immunological Findings Consistent with Expectations Explains Positive Clinical Results**

Professor Ludvigsson explained that the immunological data provided direct confirmation of the positive clinical results obtained in August 2006. They demonstrated that treatment close to disease onset provided a better clinical effect than a later in time administration of the vaccine. The new immunological findings indicate that virtually all Diamyd® treated patients, regardless of disease duration, responded immunologically, but that the clinical effect of arresting the autoimmune

attack that destroys beta cells close to disease onset is superior to a later intervention when the patient's beta cells have been almost totally destroyed.

"This may be a breakthrough in diabetes research", says Professor Johnny Ludvigsson. "There is no doubt that the GAD-vaccine has had positive effects. And it is a treatment that is very simple and without side effects. We have previously reported that the earlier a patient is treated with Diamyd®, the better are the chances that the endogenous insulin production will be preserved. Now we can state that the treatment may be relevant also at a later stage as the immunological effect observed may be a prerequisite to allow beta cell regeneration or transplanted islets or stem cells to thrive without being destroyed by recurrent autoimmune attacks."

### Potentially Groundbreaking Discovery.

"This is the first time it has been demonstrated that stimulating the immune system with an autoantigen, such as GAD65, produces a lasting immunological response, even up to 15 months after the initial vaccination", stated Anders Essen-Möller, President of Diamyd Medical. "Moreover, the results are consistent with what is expected according to the prevailing theory of how to treat autoimmune disease. This means that the successful clinical effect of Diamyd® administration is starting to be explained immunologically".

### Presentation of Additional Immunological Data and Type II Study Results.

Additional immunological data from the type 1 diabetes study will be presented in the latter part of June at the American Diabetes Association Convention (ADA) in Chicago. Importantly, results from a separate clinical study with the Diamyd vaccine in 160 patients with autoimmune type 2 diabetes (LADA) are also planned to be presented at the same ADA Convention.

#### **Initiation of Phase III Clinical Trials.**

Diamyd plans to initiate phase III studies in newly onset type 1 diabetics later this year. The US study will take place under the direction of Professor Jerry Palmer, and the Principal Investigator of the European study will be Professor Ludvigsson.

### **About Diamyd Medical**

Diamyd Medical is a life science company developing treatments for diabetes and its complications. The company's furthest developed project is the GAD-based drug Diamyd® for autoimmune diabetes. Diamyd® has demonstrated significant and positive results in Phase II clinical trials in both type 1 and autoimmune type 2 diabetes patients (LADA) in Sweden.

GAD65, a major autoantigen in autoimmune diabetes, is the active substance in Diamyd®. GAD65 is also an enzyme that converts the excitatory neurotransmitter glutamate to the inhibitory transmitter GABA. In this context GAD may have an important role not only in diabetes, but also in several central nervous system-related diseases. Diamyd Medical has an exclusive world-wide license from the University of California at Los Angeles regarding the therapeutic use of the GAD65 gene.

Diamyd Medical has sublicensed its UCLA GAD65 Composition of Matter license to Neurologix, Inc. in Fort Lee, New Jersey for treatment of Parkinson's disease with an AAV-vector.

Other projects comprise drug development within gene therapy using the exclusively licensed and patent protected Nerve Targeted Drug Delivery System (NTDDS). The company's lead gene therapy projects include using Enkephalin and GAD for chronic pain, e.g., diabetes pain or cancer pain. All projects in this field are currently in preclinical phases.

Diamyd Medical has offices in Stockholm (Sweden) and in Pittsburgh (USA). The Diamyd Medical share is quoted on the Stockholm Nordic Exchange in Sweden (ticker symbol: DIAM B) and on the OTCQX-list in the US (ticker symbol: DMYDY) administered by the Pink Sheets and the Bank of New York (PAL). Further information is available at <a href="https://www.diamyd.com">www.diamyd.com</a>

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