

## FURTHER EVIDENCE FOR LASTING IMMUNOLOGICAL EFFICACY OF DIAMYD DIABETES VACCINE

Press Release, Stockholm, Sweden, September 19, 2007 – Diamyd Medical AB (www.omxgroup.com, ticker: DIAM B; www.otcqx.com, ticker DMYDY)

Diamyd Medical announced today that further evidence for lasting immunologic efficacy of the Diamyd<sup>®</sup> diabetes vaccine, was presented at the European Association for the Study of Diabetes (EASD) conference in Amsterdam on the 18<sup>th</sup> of September 2007. The presentation confirmed that treatment with Diamyd<sup>®</sup> causes a specific immune response to GAD65 remaining even 15 months after treatment. The immunological effect was observed in patients receiving Diamyd<sup>®</sup>, but not in patients receiving placebo.

Previously it has been reported that two injections of 20 µg Diamyd® preserved beta cell function in a Phase IIb study comprising 70 children with type 1 diabetes. In that same study, immunological analyses were conducted by the team of Professor Johnny Ludvigsson, Linköping University, Sweden. The conclusion of the EASD presentation, made by Associate Professor Maria Faresjö, is that the Diamyd® vaccination induces specific T-cells that may rebalance the immune system resulting in the protective effect seen on beta cell function

Upon in vitro stimulation with GAD65, 15 months after vaccination, the immune system of Diamyd<sup>®</sup>-treated patients showed a highly statistically significant increase in the secretion of several immunomodulatory substances, dominated by regulatory cytokines, including IL5, IL13, IL10, IL17, IFN- $\gamma$  and TNF- $\alpha$ . The same immunological fingerprint was observed in virtually all Diamyd® treated patients (fig 1).

Dr. Faresjö also showed that the activity of T-cells in response to GAD65 was clearly increased in Diamyd® treated patients,

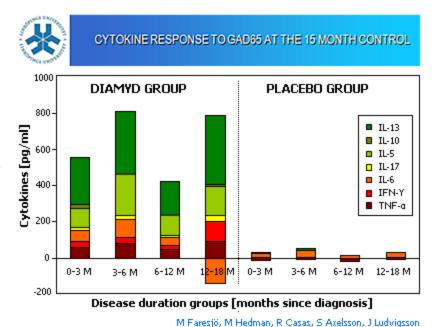


Fig 1: Patients receiving Diamyd® showed an up regulation of cytokines in response to GAD65. The immunological fingerprint of Diamyd® treated patients contained more of protective cytokines (green colors) than placebo treated patients. Placebo patients secreted a higher percentage of inflammatory cytokines (red colors) than the treated patient. This may explain the protective effect on beta cell function of Diamyd® treatment.

measured as GAD65 induced FOXP3 expression.

"This is the first time that biomarkers have been identified that correlate with immunological efficacy using an autoantigen specific therapy in the clinic", says the internationally renowned immunologist Professor Bart Roep, Leiden University Medical Center, The Netherlands. "Furthermore, these results show evidence of immune markers that correlate with clinical efficacy, providing another novelty in immune intervention therapy in autoimmune diseases. Perhaps the most astonishing finding is the persistence of immune changes many months after therapy, which implies a lasting impact of Diamyd<sup>®</sup> on autoimmune deviation. I congratulate Professor Ludvigsson and his team on their pioneering clinical studies that led to this breakthrough."

Type 1 diabetes is an autoimmune disease where the insulin producing beta cells are under attack from the patients own immune system. The Diamyd® vaccine is aimed at inducing active functional tolerance to beta cells by means of administering a major beta cell autoantigen (GAD65) in a formulation and route designated to rebalance the immune system. This is believed to arrest or slow down the autoimmune process in type 1 diabetes.

## **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 for which Phase III studies are planned to be initiated this year. Diamyd® has demonstrated significant and positive results in Phase II clinical trials 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 worldwide license from the University of California at Los Angeles regarding the therapeutic use of the GAD65 gene.

Diamyd Medical has sublicensed its UCLA GAD 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 therapeutic gene transfer using the exclusively licensed and patent protected Nerve Targeted Drug Delivery System (NTDDS). The company's lead NTDDS 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 Pittsburgh, PA. The Diamyd Medical share is quoted on the Stockholm Nordic Exchange in Sweden (NOMX ticker: DIAM B) and on the OTCQX-list in the United States (ticker: DMYDY) administered by the Pink Sheets and the Bank of New York (PAL). Further information is available at www.diamyd.com.

For further information, please contact:

Stockholm office Anders Essen-Möller CEO and President +46 8 661 0026 investor.relations@diamyd.com Pittsburgh office Michael Christini President +1 412 770 1310 Michael.Christini@diamyd.com

## Diamyd Medical AB (publ). Linnégatan 89 B, SE-115 23 Stockholm, Sweden. Tel: +46 8 661 00 26, fax: +46 8 661 63 68 or E-mail: info@diamyd.com. VATno: SE556530-142001.

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