



DIAMYD FILES US IND FOR PHASE III TRIAL WITH DIABETES VACCINE

Press Release, Stockholm, Sweden, December 21, 2007 – Diamyd Medical AB
(www.omxgroup.com, ticker: DIAM B; www.otcqx.com, ticker DMYDY)

Diamyd Medical announced today that it has filed an Investigational New Drug (IND) application for a pivotal US Phase III clinical trial with the Diamyd[®] therapeutic vaccine in recent onset type 1 diabetes patients. The application was submitted to the US Food and Drug Administration (FDA).

Similar applications for a parallel European Phase III trial are planned to be submitted to European regulatory agencies. Diamyd Medical anticipates that two successful Phase III studies, each comprising 300 recent onset type 1 diabetes patients, may lead to market approval.

The Diamyd[®] therapeutic vaccine is intended to arrest or slow down the autoimmune destruction of insulin producing beta cells in type 1 diabetes. Diamyd[®] has demonstrated significant efficacy in Phase II clinical trials in preservation of beta cell function for at least 21 months. Additionally, no treatment-related serious adverse events have been observed, providing Diamyd[®] with a strong safety profile.

“A newly diagnosed type 1 diabetes patient might face a lifetime of complications from the disease despite conventional therapy with insulin injections. In this context, Diamyd[®] has a remarkable potential as a novel therapy filling a desperately unmet medical need,” says Elisabeth Lindner, President and CEO of Diamyd Medical. “The filing of the Diamyd[®] IND and a receipt of approval thereafter are prerequisites for conducting confirmatory studies in larger patient populations in the US and important steps towards making the Diamyd[®]-vaccine available to the patients.”

“Preservation of beta cell function in type 1 diabetes patients is an important step towards finding a cure for type 1 diabetes and paving the way for beta cell regeneration, stem cell and transplantation therapies,” says Professor Jerry Palmer, Head of Diabetes Endocrinology Research Center at the University of Washington in Seattle, US, who will take the role as lead investigator in the planned US Phase III study. “Endogenous insulin production makes it easier for the patients to manage their disease and there should be less late-stage complications. I am proud to take Diamyd[®] to the next level.”

As previously announced, the Phase III trials will evaluate the effectiveness and safety of Diamyd[®] in patients that have had type 1 diabetes for up to three months. Based upon previous discussions with the FDA, meal-stimulated C-peptide, as a correlate for the patient’s own insulin production, will be the primary endpoint. Insulin requirement and glycemic endpoints will also be measured and results will be evaluated after 15 months.

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. 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.

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