

## DIAMYD UPDATES FDA IND APPROVAL STATUS FOR PHASE III DIAMYD<sup>®</sup> DIABETES STUDY IN THE US

## *Press Release, Stockholm, Sweden, February 12, 2008 – Diamyd Medical AB* (www.omxgroup.com, ticker: DIAM B; www.otcqx.com, ticker DMYDY)

Diamyd Medical announced today that it has received one FDA question relating to the US Phase III IND application for Diamyd<sup>®</sup> in treatment of type 1 diabetes. The question has been answered with additional documentation and the FDA now has 30 days to respond.

"Our Phase III IND file contains extensive documentation and a rigorous review by the FDA identified only one manufacturing question that required submission of additional data," stated Elisabeth Lindner, CEO of Diamyd Medical. "We have worked diligently with our Drug Product manufacturing contractor last week to compile the data and the matter has now been fully addressed. Considering the nature of a Phase III application requiring very extensive documentation, we are very satisfied with this outcome. Importantly, to date no immediate modifications for our clinical trial design have been requested by the FDA and we anticipate starting the Phase III clinical program according to plan."

The US Phase III clinical trial is a double-blind study including approximately 300 new onset type 1 diabetes patients. A similar Phase III trial is planned for Europe, which has been initiated with a clinical trial application in Sweden.

In parallel with the Diamyd<sup>®</sup> Phase III program, NIH/NIDDK with TrialNet are planning a study with 126 new onset type 1 diabetes patients to further evaluate efficacy and mechanism of action of Diamyd<sup>®</sup>.

## About Diamyd Medical

Diamyd Medical is a biopharmaceutical company developing treatments for diabetes and its complications. The company's furthest developed project is the GAD-based drug Diamyd<sup>®</sup> for autoimmune diabetes for which Phase III studies are planned. Diamyd<sup>®</sup> 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.

Other projects comprise drug development within therapeutic gene transfer using the exclusively licensed

and patent protected Nerve Targeting Drug Delivery System (NTDDS). The company's lead NTDDS projects include enkephalin and GAD for chronic pain, e.g., diabetes pain or cancer pain.

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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