Press Release, June 23, 2011

# Diamyd initiates closure of US Phase III study

*Diamyd Medical AB reports that the Company has decided to suspend dosing in a US Phase III study with the antigen-based therapy Diamyd® and to initiate closure of the study.*

Following consultation with the US Food and Drug Administration (FDA), Diamyd Medical has decided to suspend dosing in its US Phase III study, DiaPrevent, with the antigen-based therapy Diamyd®. Study closure activities will commence promptly. The decision follows a blinded review of the efficacy data collected to date in the study as well as the previously reported negative outcome of a European Phase III study of the same design.

"It is sad to report that we are terminating the current Phase III program with Diamyd®," says Peter Zerhouni, Acting President and CEO of Diamyd Medical. "Our review of the available data suggests the DiaPrevent study is not likely to reach a positive outcome regarding efficacy and therefore it cannot be justified to complete the study as originally planned. However, the safety profile remains good. We want to express our sincere gratitude to all the study participants, as well as their families and the many doctors and nurses in the study."

The Phase III study conducted in the US, called DiaPrevent, has enrolled more than 320 patients between 10 and 20 years of age who were diagnosed with type 1 diabetes within three months of entering the study. The study includes three treatment arms in which one-third of the patients were scheduled to receive four subcutaneous injections of Diamyd®; one-third to receive two injections of Diamyd®; and one-third to receive placebo (non-active substance). The injections were to be given over a period of 9 months. The last patient randomized into the study received the first injection of Diamyd® or placebo in December 2010. The study included a main study period of 15 months, but this will now be shortened.

On May 9, 2011, the Company reported that its parallel European Phase III study with Diamyd® did not meet the primary efficacy endpoint of preserving beta cell function at 15 months, as measured by meal stimulated C-peptide, although a small positive effect was seen. Furthermore, Diamyd® was well tolerated as demonstrated by a similar number of adverse events in the Diamyd® treated groups as well as in the placebo treated group. The follow-up period of the European Phase III study was closed on June 1, 2011. Detailed results from the European study will be presented at the American Diabetes Association's 71st Scientific Sessions (ADA) in San Diego, CA, USA, on June 28, 2011.

The research consortium Type 1 Diabetes TrialNet is conducting a Phase II trial with Diamyd® in the US and Canada with a similar study design. Results from that study will also be presented at the ADA in San Diego, on June 27, 2011.

An externally funded and researcher-initiated Phase II study with Diamyd® aiming to prevent type 1 diabetes in children at high risk of developing the disease is in progress. That study is not affected by the findings in the two Phase III trials.

"We remain hopeful that Diamyd® and the active substance GAD65 can be effective if administered earlier in the disease process to prevent type 1 diabetes, in certain subgroups, in combination with other drugs or in a different treatment regimen," says Peter Zerhouni. "Immunological data collected in our European Phase III study has yet to be reviewed and will guide us in setting the future plan for Diamyd® and GAD65."

**For more information, please contact:**
Peter Zerhouni, Acting President and CEO Diamyd Medical AB (publ.)
Phone: +46 8 661 0026

**For press material, please contact:**
Andreas Ericsson, Diamyd Medical AB (publ.)
press@diamyd.com
Phone: +46 8 661 0026

**About the diabetes therapy Diamyd®**
Diamyd® is an antigen-based diabetes therapy under development. The active substance in Diamyd® is the human protein GAD65 (Glutamic acid decarboxylase isoform 65 kDa). The development has been ongoing since 1994 when Diamyd Medical signed an exclusive license to patents and patent applications related to the GAD65-molecule with the University of California, Los Angeles (UCLA).

The purpose of the therapy is to prevent, delay, or stop the autoimmune attack on beta cells in type 1 diabetes and other forms of autoimmune diabetes, thereby preserving the body's capacity to regulate blood sugar. This reduces the risk for both acute and long term diabetes complications significantly. A Phase II study of 70 children and adolescents with type 1 diabetes published in The New England Journal of Medicine in 2008 showed that Diamyd® significantly slowed the progression of the disease in subjects treated within 18 months of being diagnosed with type 1 diabetes.

**About Diamyd Medical**
Diamyd Medical is a Swedish pharmaceutical company focusing on the development of pharmaceuticals for the treatment of autoimmune diabetes and pain. The Diabetes business area consists of the antigen-based drug candidate Diamyd® for the treatment and prevention of autoimmune diabetes. The Pain business area consists of development projects that use the Company's proprietary NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs directly to the nervous system to treat chronic pain. A Phase II study of the candidate drug NP2 Enkephalin for cancer pain is ongoing in the US.

Diamyd Medical has offices in Sweden and in the US. Shares are listed on Nasdaq OMX in Stockholm (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY) administered by the Pink OTC Markets and the Bank of New York Mellon (PAL). Further information is available on the company's website: www.diamyd.com.

*This information is disclosed in accordance with the Swedish Securities Markets Act, the Swedish Financial Instruments Trading Act, or the requirements stated in the listing agreements.*

**Diamyd Medical AB (publ.)**
Karlavägen 108, SE-115 26 Stockholm, Sweden. Tel: +46 (0)8 6610026, Fax: +46 (0)8 661 63 68
E-mail: info@diamyd.com. VAT no: SE556530-142001