



Press Release, June 1, 2011

Diamyd closes European Phase III study

Diamyd Medical AB reports that the Company has decided not to complete the follow-up period of a European Phase III study with the antigen-based therapy Diamyd®.

On May 9, the Company reported that its European Phase III study with the antigen based therapy 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.

As part of a planned, longer-term follow-up, patients in the study were being followed for an additional 15 months, aiming to determine the durability of the treatment effect at 30 months. Following comprehensive evaluation of the collected study data, Diamyd Medical has decided not to complete the follow-up period.

“Given that the European Phase III study did not meet the primary efficacy endpoint, it is difficult to justify continuing the follow-up period, although the results suggest beneficial effects in certain subgroups,” says Peter Zerhouni, Acting President and CEO of Diamyd Medical. “We would, once again, like to express our sincere gratitude to all the study participants, as well as their families and the many doctors and nurses who made the study possible. Our parallel US Phase III study, DiaPrevent, continues and we hope it will result in a different outcome.”

The European Phase III study 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 received four subcutaneous injections of Diamyd®; one-third received two injections of Diamyd®; and one-third received placebo (non-active substance). The patients have been followed for at least 6 months after receiving the last injection of Diamyd® or placebo, fulfilling the main study period of 15 months and the study drug was well tolerated. Detailed results from the study will be presented at the American Diabetes Association's 71st Scientific Sessions in San Diego, CA, USA, June 24-28, 2011.

An ongoing parallel US Phase III study, DiaPrevent, was fully enrolled in December 2010, and results are expected in the summer of 2012. In addition, the research consortium Type 1 diabetes TrialNet is conducting a Phase II trial with Diamyd® in the US and Canada with similar design. Another externally funded and researcher-initiated Phase II study with Diamyd® in progress is aiming to prevent type 1 diabetes from developing in high risk subjects.

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