

Press Release, February 14, 2011

Last patient completes the EU Phase III study of Diamyd[®] antigen based therapy for type 1 diabetes

The final patient has performed the last visit of the main study period in Diamyd Medical's European Phase III study. Treatment with the antigen based therapy Diamyd[®] is made to investigate whether beta cell function and thereby blood sugar control can be preserved in children and adolescents with new onset type 1 diabetes. The top line results from this study are expected to be reported as planned, in late spring 2011.

The last patient in the EU Diamyd Phase III clinical study has completed the 15-month visit, meaning that all patients in this study have completed the main 15 month study period in this trial. This important achievement in the Diamyd[®] Phase III program will now be followed by an intense period where the data will be compiled from the more than 60 clinics throughout Europe and from the central laboratory. The extensive work of data compilation and processing will continue for the next months, after which the study will be unblinded. The top line results are expected to be reported as planned, in late spring 2011. With good results, Diamyd intends to apply for market approval by the end of this year.

"This is an extremely important period not only for Diamyd Medical, but also for the physicians who perform this study as well as for all the children, adolescents and parents who have chosen to participate in the study. The results are also of tremendous importance for the entire field of diabetes research," says **Elisabeth Lindner**, CEO and President of Diamyd Medical.

The first patient in the Diamyd EU Phase III study was enrolled in the autumn of 2008, and the trial was fully recruited in November 2009. All patients have now been followed for 15 months, which is the main study period for this trial. As part of a planned, longer term follow on study, the patients will be followed for an additional 15 months, to further evaluate the safety and efficacy of the antigen based therapy Diamyd[®].

The EU Phase III study is a multinational, multicenter, double-blind, randomized, placebo-controlled trial enrolling approximately 320 patients between 10 and 20 years of age who have been diagnosed with type 1 diabetes within three months. The study is being conducted at more than 60 clinics in nine European countries, i.e. Finland, France, Germany, Holland, Italy, Slovenia, Spain, Sweden and UK. One third of the patients received four injections with Diamyd[®], one third received two injections with Diamyd[®] followed by two injections with placebo, and one third has received four injections with placebo. The injections were given on Day one, and then after one month, three months and nine months.

In its global Phase III program, Diamyd is also conducting a similar study in the U.S., DiaPrevent, which was fully enrolled in December 2010. Diamyd expects to complete the main study period of this study during the spring of 2012.

The global Phase III program aims to investigate whether Diamyd[®] can halt or slow the destruction of beta cells in the pancreas in type 1 diabetes, preserving the beta cell function and the body's own ability to control the blood sugar level. This in turn reduces the risk of both short and long term diabetes complications. In Phase II studies, the Diamyd[®] therapy has been shown to slow the loss of beta cell function compared to placebo.

The two studies have now enrolled more than 640 recently diagnosed type 1 diabetes patients between 10 and 20 years of age in Europe and USA.

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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. Phase III studies of Diamyd[®] are currently in progress in Europe and the US. In 2010 the Company signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc., for the development and commercialization of Diamyd[®]. 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: <u>www.diamyd.com</u>.

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.

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