Press release, February 5, 2009

Diamyd® combination trial aimed at regenerating insulin-producing capacity in established type 1 diabetes gets approval from FDA

Diamyd Medical reports that the US Food and Drug Administration (FDA) has approved a study designed to preserve and possibly regenerate insulin production in patients with recent onset type 1 diabetes. The trial will test the diabetes vaccine Diamyd® in combination with drugs that are believed to stimulate new beta cell growth. The aim of the combination therapy is to try to restore lost insulin-producing capacity in established type 1 diabetes patients.

The study will be carried out and funded by the National Institute of Diabetes and Kidney Disease (NIDDK), which is part of the National Institutes of Health (NIH) in Bethesda, MD, USA. Diamyd Medical has developed the clinical protocol together with NIDDK researchers and will be free to use the study results. Ethics approval has already been received, and screening of patients for the study will start in the next few weeks.

This new Phase II study will be the first to combine regenerative agents and Diamyd®. The regenerative agents to be evaluated are lansoprazole and sitagliptin, which are both marketed drugs in the US. The study, to be led by Professor **David Harlan** at NIDDK, aims to enroll 82 adult patients. "We are excited to start this study to investigate if combining Diamyd® with potentially regenerative stimuli can meaningfully improve treatment of established type 1 diabetes", says Professor Harlan, chief of the Diabetes Branch at NIDDK and professor of medicine at the Uniformed Services University of the Health Sciences.

In type 1 diabetes, insulin-producing cells are gradually destroyed by the immune system. In early clinical trials, the Diamyd® vaccine has been shown to slow the immune attack in recent-onset type 1 diabetes. Researchers hypothesize that by targeting the immune attack with the Diamyd® diabetes vaccine and simultaneously stimulating development of insulin-producing cells, a person's ability to produce insulin may be preserved and may even be improved. Even a modest preservation of insulin-producing capacity makes diabetes significantly easier to control, which reduces the risk of diabetes complications that cause immeasurable suffering for patients and high costs for society.

Diamyd Medical is also collaborating with the Type 1 Diabetes TrialNet network, which is initiating a study with Diamyd® in 126 patients. Other collaborations involve two prominent type 1 diabetes research groups in the Nordic countries.

"For a small company like Diamyd Medical, cooperating with the world's leading diabetes institutions to carry out research studies is a very cost efficient model, because it allows us to focus our own resources on the ongoing Phase III trials," says **Elisabeth Lindner**, President and CEO of Diamyd Medical. "We are, of course, very happy that we are able to explore Life Cycle Management options for Diamyd® with the support of key experts in the field, without having to allocate financial resources."

Diamyd Medical AB (publ.)

Linnégatan 89 B, SE-115 23 Stockholm, Sweden. Phone: +46 8 661 00 26, Fax: +46 8 661 63 68

E-mail: info@diamyd.com. VATno: SE556530-142001.

"With this combination study, Diamyd is continuing its strategic path of development for Diamyd® for type 1 diabetes," continues Elisabeth Lindner. "We have shown that Diamyd® as a mono-therapy could preserve insulin-producing capacity in recent-onset type 1 diabetes, as reported in the New England Journal of Medicine on October 30, 2008. We have a large scale Phase III program running in Europe and the US that will support this market registration.

In December, study protocols were filed with regulatory authorities in two Nordic countries for clinical studies aimed at preventing type 1 diabetes in subjects at high risk of developing the disease.

Treatment of recent-onset patients, prevention in risk patients, and combination therapy in patients with established disease are the three treatment strategies envisioned for type 1 diabetes."

For more information, please contact:
Elisabeth Lindner, President and CEO Diamyd Medical AB (publ.), elisabeth.lindner@diamyd.com
Phone: +46-8-661 0026

For pictures and press material, please contact:
Sonja Catani, Chief Communications Officer Diamyd Medical AB (publ.), sonja.catani@diamyd.com
Phone: +46-8-661 00 26

This information is disclosed in accordance with the Securities Markets Act, the Financial Instruments Trading Act or demands made in the exchange rules.

Diamyd Medical is a Swedish biopharmaceutical company focusing on development of pharmaceuticals for treatment of autoimmune diabetes and its complications. The company's most advanced project is the GAD-based drug Diamyd® for type 1 diabetes, for which Phase III trials are ongoing in both the US and Europe. Furthermore, the company has initiated clinical studies within chronic pain, using its Nerve Targeting Drug Delivery System (NTDDS). The company has also out-licensed the use of GAD for the treatment of Parkinson's disease.

Diamyd Medical has offices in Sweden and in the US. The share is quoted on the OMX Stockholm Nordic Exchange (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY) administered by the Pink Sheets and the Bank of New York (PAL). Further information is available on the company's web site: www.diamyd.com