Press Release, May 9, 2011

Diamyd reports initial results from European Phase III trial in patients newly diagnosed with type 1 diabetes

Diamyd Medical AB reports that results from 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, in newly diagnosed type 1 diabetes patients.

In Diamyd Medical's European Phase III study in recently diagnosed type 1 diabetes patients, 10 to 20 years old, the antigen-based therapy, Diamyd®, did not show a statistically significant preservation of beta cell function after 15 months of follow-up compared to placebo, although a small positive effect was seen. Furthermore, Diamyd® was well tolerated as demonstrated by a similar number of adverse events across treatment groups. Detailed results will be presented at the American Diabetes Association's 71st Scientific Sessions in San Diego, CA, USA, June 24-28, 2011.

As part of a planned, longer-term follow-up, the patients in the European study are currently being followed for an additional 15 months to further evaluate the safety and efficacy of Diamyd®. An ongoing parallel U.S. Phase III study, DiaPrevent, was fully enrolled in December 2010, and results are expected in the summer of 2012. Several externally funded and researcher-initiated studies are also in progress, including a Phase II study aiming to prevent type 1 diabetes from developing in high risk subjects.

"Although we had hoped for a better outcome of the European Phase III trial, we will now further analyze the study results together with data from other ongoing studies to better understand and determine the precise therapeutic impact of this approach as well as the best path forward for the program," says Peter Zerhouni, Acting President and CEO of Diamyd Medical. "Our vision to find a cure for type 1 diabetes remains firm, and I would like to thank all the study participants, as well as their families and the many doctors and nurses who dedicate themselves to the conduct of this study."

The European Phase III study evaluating Diamyd® is a multinational, multicenter, double-blind, randomized, placebo-controlled trial. The primary efficacy variable of the study is meal stimulated C-peptide as a measure of beta cell function. The study is being conducted at more than 60 clinics in nine European countries: Finland, France, Germany, Italy, the Netherlands, Slovenia, Spain, Sweden and the UK. The 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® (days 1, 30, 90 and 270); one-third received two injections of Diamyd® (days 1 and 30); and one-third received placebo (non-active substance). The CRO, Contract Research Organization, of the study is TFS Trial Form Support AB.

In 2010 the Company signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc., (OMJPI) for the development and commercialization of Diamyd®. Under the agreement, OMJPI has the right to fully assume responsibility for the global development upon completing its own review of the Phase III results.

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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. Phase III studies of Diamyd® are currently in progress in Europe and the US. 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.

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