Press Release, June 28, 2011

Diamyd presents detailed results of European Phase III study

Diamyd Medical AB reports detailed results from the Company's European Phase III study of the antigen-based diabetes therapy Diamyd®, which, as previously announced, did not meet the primary efficacy endpoint.

Today, June 28, at the "American Diabetes Association's 71st Scientific Sessions" in San Diego, California, USA, lead investigator Dr. Johnny Ludvigsson presents the detailed results of Diamyd Medical's European Phase III study of the antigen-based diabetes therapy Diamyd®.

The study enrolled 334 patients, 10 to 20 years old, who were diagnosed with type 1 diabetes within three months of entering the study. All of the patients had some endogenous insulin production left and were GAD antibody positive at study entry. The study included three treatment arms in which a third of the patients received four subcutaneous injections of Diamyd® (day 1, 30, 90 and 270), one third received two injections of Diamyd®, and one third received placebo (non-active substance). Patients were followed for 15 months. Diamyd® was well tolerated, as demonstrated by a similar number of adverse events reported in the groups treated with Diamyd® and the placebo group. The levels of GAD antibodies increased significantly in the groups receiving Diamyd®, but not in the placebo group.

The primary efficacy endpoint was change in C-peptide, a measure of endogenous insulin production, between the first study visit and the visit 15 months later. In the study, the levels of C-peptide decreased similarly in all treatment groups and, as previously reported, the primary efficacy endpoint was not met, although a small positive effect was seen. Patients treated with Diamyd® had on average 16.4 percent more remaining C-peptide at 15 months compared to those who received placebo. The p-value of the primary endpoint was 0.10. The secondary efficacy endpoints included mean daily dose of insulin, hemoglobin A1c (HbA1c) and frequency of hypoglycemia. Treatment with Diamyd® did not achieve a statistically significant effect for any secondary endpoint.

"I am naturally disappointed over the outcome of the study and surprised that we did not see a greater overall effect given previous studies," said Dr. Johnny Ludvigsson, lead investigator and professor at Linköping University. "However, we cannot reject this treatment based on the fact that this study did not reach statistical significance. We must learn from other therapeutic areas, like allergy and cancer, which have advanced by combining different treatments, each of which may have limited effect. It is also possible that the treatment is effective in prevention of type 1 diabetes."

Pre-specified subgroup analyses suggest that Diamyd® had an effect in several subgroups. These analyses included divisions based on gender, age, country, number of days since diagnosis at baseline and other characteristics. In the subgroup of male study participants the patients treated with Diamyd® kept 41 percent more of their C-peptide than those who received placebo ($p < 0.01$).

"Although subgroup analyses must be interpreted with great caution and require confirmation in other studies, our results indicate that Diamyd® and the active ingredient GAD65 may preserve the body's own insulin production in certain subgroups of patients," says Dr. Ludvigsson.

Another interesting observation was that among the patients who received their first injection of Diamyd® during the period March-April, the patients treated with Diamyd® kept significantly more of their C-peptide than the corresponding placebo-treated patients ($p = 0.02$). In the previous Phase II study with Diamyd®, all study participants received their first injection of study drug during these months and since there are seasonal variations in the immune system this may play a role for the treatment's effect on the immune system. Another factor that could contribute to the difference in outcomes between Phase II and Phase III is the use of influenza vaccine during the study periods.

During the Phase III study, there was a pandemic influenza outbreak that led to many vaccinations in the study even though, originally, it was not planned to allow for influenza vaccination in conjunction with injections of study drug. Among the patients who were not vaccinated against influenza within 150 days after the first injection of Diamyd® or placebo, the p-value was 0.07.

Given that the European Phase III study did not meet the primary efficacy endpoint, Diamyd Medical decided not to complete the follow-up period of the study, which therefore was closed on June 1 this year. On June 23 the Company announced the decision to suspend dosing in a parallel US Phase III study and to also initiate closure of that study.

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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. 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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