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New clinical study with Diamyd's diabetes vaccine

Diamyd Medical AB reports that a new clinical study with the diabetes vaccine Diamyd® is planned to start in February 2013. In the study Diamyd® will be tested in a unique combination with other drugs, aiming to potentiate the effect of the diabetes vaccine. The Company has entered into an agreement with Linköping University to conduct the researcher-initiated study. The study has been approved by the Swedish Medical Products Agency.

The study, which is the first study of its kind, combines the diabetes vaccine Diamyd® with relatively high doses of vitamin D and the anti-inflammatory drug ibuprofen. The purpose of the treatment is to preserve the body's own ability to control the blood sugar level in children and adolescents newly diagnosed with type 1 diabetes.

"I am excited to start this new important study and I strongly believe in combining Diamyd® with vitamin D and anti-inflammatory drugs," says Professor Johnny Ludvigsson at Linköping University, principal investigator and sponsor of the study. "The aim of the combination is to create favorable conditions for the diabetes vaccine Diamyd® to take effect by temporarily dampen the inflammation in the pancreas, while vitamin D is believed to strengthen the part of the immune system that Diamyd® should stimulate."

The study is called DIABGAD-1 and will also evaluate the effect of a double dose of Diamyd® and the protein GAD, which is the active substance in Diamyd®. The study will include 60 children and adolescents in Sweden and it will be conducted at pediatric diabetes clinics in Malmö, Lund, Halmstad, Kalmar, Jönköping, Uddevalla, Örebro, Linköping and Stockholm. The study is funded by research grants, while Diamyd Medical is responsible for providing study drug and certain other costs, and can utilize the study results.

"Diamyd Medical's collaboration with the researchers in this pilot study is a good example of our strategy to evaluate different treatment concepts with the diabetes vaccine Diamyd® through externally funded clinical trials," says Peter Zerhouni, President and CEO of Diamyd Medical. "We strongly believe in attacking the disease process in type 1 diabetes from several sides simultaneously through the combination of different drugs, and this is one of the first such studies in the world. By following immunological markers the study period has been shortened and it will provide new and important insights for the further commercial development of our diabetes vaccine."

DIABGAD-1 is a double-blind, randomized and placebo-controlled Phase II study including a total of 60 participants between 10 and 18 years old, newly diagnosed with type 1 diabetes. The study will comprise a total of 30 months, with a first analysis focusing on immunological markers already after 6 months. The study has been approved by the Swedish Medical Products Agency and is scheduled to start screening patients in the beginning of February 2013. Four different treatment groups, each including 15 participants, will be evaluated: the first group will receive one prime injection of Diamyd® and a booster injection 4 weeks later, combined with ibuprofen for 90 days and vitamin D for 450 days; the second group will receive one prime injection of Diamyd® and a booster injection 4 weeks later, and vitamin D for 450 days; the third group will receive two prime injections of Diamyd® and two booster injections 4 weeks later, and vitamin D for 450 days; and the fourth group will receive placebo only.

About type 1 diabetes and the diabetes vaccine Diamyd®

Type 1 diabetes, also known as juvenile diabetes, is a lifelong and very serious disease that often affects young children. It is an autoimmune disease caused by the body's own immune system attacking and destroying the insulin secreting beta cells in the pancreas, resulting in insulin deficiency and inability to control blood sugar levels. There is currently no treatment on the market addressing the autoimmune process that causes type 1 diabetes.

Current treatment strategies involve controlling the blood sugar level by adding external insulin, either by injections or by insulin pump. The aim is to reach as stable a blood sugar level as possible, neither too high nor too low. Consistently high and fluctuating blood sugar levels cause diabetes complications, including kidney and eye damage, cardiovascular disease, nerve damage as well as severe hypoglycemia and ketoacidosis.

Diamyd Medical's drug development in diabetes originates from the protein GAD, which is the active substance in the Company's diabetes vaccine Diamyd® for the prevention and treatment of autoimmune diabetes. Treatment with Diamyd® is intended to prevent, delay, or stop the autoimmune attack on the beta cells. The aim is to prevent the onset of autoimmune diabetes, or to preserve the body's capacity to regulate blood sugar. Studies have shown that even a very small preservation of endogenous insulin secretion and slight improvement of the blood sugar control can significantly reduce the risk of both acute and long-term diabetes complications.

Since 2009 the diabetes vaccine Diamyd® is being evaluated in a Swedish researcher-initiated Phase II study, DiAPREV-IT. That study includes a total of 50 children aged four and older who, through analysis of diabetes markers in the blood, are demonstrated to be at high risk of developing type 1 diabetes, but have not yet presented with disease. The purpose of the study is to evaluate whether preventive treatment with Diamyd®, compared to placebo, can delay or halt the progression of the disease so that the children do not develop clinical symptoms of type 1 diabetes. The first results are expected to be compiled in 2015.

For more information, please contact:

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About Diamyd Medical

Diamyd Medical was founded in 1996 and is active in the field of pharmaceutical development. Diamyd Medical is headquartered in Stockholm, Sweden. The Company's development project consists of the protein GAD for the treatment and prevention of autoimmune diabetes. A Swedish researcher-initiated Phase II study is ongoing to evaluate whether GAD can prevent type 1 diabetes in children who are at high risk of developing the disease.

Diamyd Medical also has holdings in the gene therapy company Periphagen Holdings, Inc. (USA), the vaccine company Protein Sciences Corporation (USA) and the diagnostics company Mercodia AB (Sweden).

Diamyd shares are listed on Nasdaq OMX (segment Small Cap) 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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