



Press release, June 9, 2014

Clinical study with Diamyd Medical's diabetes vaccine fully recruited

All participants have been included in a Phase II clinical study, DIABGAD-1, in which Diamyd Medical's diabetes vaccine Diamyd[®], in a unique combination with other drugs, is tested in children and adolescents recently diagnosed with type 1 diabetes. The first results from the researcher initiated study will thereby be available in the beginning of 2015.

The study, DIABGAD-1, which is the first study of its kind, combines the diabetes vaccine Diamyd[®] with vitamin D and the anti-inflammatory drug ibuprofen. The Phase II study also evaluates the effect of a double dose of Diamyd[®] and the protein GAD, which is the active substance in Diamyd[®]. The purpose of the treatment is to preserve the body's own insulin producing capacity and ability to control the blood sugar level in children and adolescents newly diagnosed with type 1 diabetes.

The study will continue for a total of 30 months after all participants have been included, with a first analysis focusing on immunological markers already after 6 months. Since the final participant now has been included, the first analysis will be initiated at the end of 2014 and the results can be presented in the beginning of 2015.

“We strongly believe in attacking the disease process underlying type 1 diabetes simultaneously from several angles through the combination of our diabetes vaccine Diamyd[®] with other therapeutics, and this is one of the first such studies in the world,” says Peter Zerhouni, President and CEO of Diamyd Medical. “I am very happy and grateful that so many children and adolescents with their families have chosen to participate in the study and also for the strong commitment from the clinical researchers and other staff.”

The study is conducted at nine pediatric diabetes clinics in Sweden. It is researcher initiated and led by Professor Johnny Ludvigsson at Linköping University. The clinics have now included a total of 64 children and adolescents, between 10 and 18 years of age, recently diagnosed with type 1 diabetes.

“I am extremely excited this important study is now fully recruited,” says Professor Johnny Ludvigsson at Linköping University, principal investigator and sponsor of the study. “The aim of the combination therapy is to create favorable conditions for the diabetes vaccine Diamyd[®] to take effect by temporarily dampen the inflammation in the pancreas with ibuprofen, while vitamin D is believed to strengthen the part of the immune system that Diamyd[®] should stimulate. In this study we also try to shorten the study period by analyzing immunological markers already after 6 months, which will provide new and important insights for the further development of the diabetes vaccine.”

About DIABGAD-1

DIABGAD-1 is a double-blind, randomized and placebo-controlled Phase II study including a total of 64 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 after 6 months. Four different treatment groups, each including approximately 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 additional booster injections 4 weeks later, and vitamin D for 450 days; and the fourth group will receive placebo only (no active substance). Chance will decide which treatment group a patient is randomized to and nobody knows who is randomized to which group. The study is conducted at pediatric diabetes clinics in Malmö, Lund, Halmstad, 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.

About type 1 diabetes and the diabetes vaccine Diamyd®

Type 1 diabetes is an autoimmune form of diabetes that ordinarily occurs in children. The disease is caused by an autoimmune attack, which means that the body's own immune system destroys the insulin-producing beta cells in the pancreas that control the blood sugar. To survive with type 1 diabetes intensive treatment with insulin is needed every day for life, either through injections or an insulin pump, and the blood sugar must be checked through blood samples 7-10 times a day. Both too much and too little insulin can lead to unconsciousness and even death. Type 1 diabetes can also cause serious long-term complications, such as blindness, cardiovascular disease, nephropathy and neuropathy. Today there is no cure for type 1 diabetes and the disease cannot be prevented.

Diamyd Medical's diabetes vaccine Diamyd® is intended to prevent, delay, or stop the autoimmune attack on the beta cells. The aim is to prevent the onset of diabetes, or to preserve the body's remaining capacity to regulate blood sugar. Studies have shown that even a very limited preservation of endogenous insulin secretion and a slight improvement of the blood sugar control significantly reduce the risk of both acute and long-term diabetes complications.

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About Diamyd Medical

Diamyd Medical is a Swedish diabetes company. The Company's primary development project consists of the GAD-based diabetes vaccine Diamyd® for the treatment and prevention of autoimmune diabetes. Two Swedish researcher-initiated Phase II studies with Diamyd® are currently ongoing. One study evaluates whether the diabetes vaccine can prevent type 1 diabetes in children who are at high risk of developing the disease, while the other study evaluates whether Diamyd® in combination with vitamin D and ibuprofen can preserve the body's own ability to regulate the blood sugar level in children and adolescents newly diagnosed with type 1 diabetes.

In 2013 the Company concluded an exclusive licensing agreement with the University of California in Los Angeles (UCLA) relating to a patent portfolio for the therapeutic use of GABA (gamma-aminobutyric acid) and GABA receptor agonists for the treatment and prevention of type 1 and type 2 diabetes and other inflammation-related conditions, such as metabolic syndrome, rheumatoid arthritis and allergies.

In April 2014, Diamyd Medical entered an agreement with a group of founding partners and Karolinska Institutet Holding AB, in order to establish a commercial cord blood bank in Sweden for private family saving of umbilical cord blood and other sources of stem cells. The intention is also to collect and make available stem cells from umbilical cord tissue for research purposes in

order to advance the fields of stem cells and regenerative medicine, including research within type 1 diabetes.

Diamyd Medical also has interests in the gene therapy company Periphagen Holdings, Inc. (US) and Companion Medical, Inc. (US).

Diamyd Medical's Series B share is traded on NASDAQ OMX First North under the ticker DMYD B. Remium Nordic AB is the Company's Certified Adviser. Further information is available on the Company's website: www.diamyd.com.

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