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Prevention study with Diamyd's diabetes vaccine fully recruited

A total of 50 children aged four and older with a high risk of developing type 1 diabetes have been enrolled in a researcher-initiated Phase II study, DiAPREV-IT, with Diamyd Medical's diabetes vaccine Diamyd®. The study is thus fully recruited. The purpose of the study is to evaluate whether preventive treatment with Diamyd® can delay or halt the progression of the disease so that the children do not develop clinical symptoms of type 1 diabetes.

The children enrolled in the study are healthy, but have all been found to have an ongoing autoimmune process, where their blood sugar-regulating beta cells in the pancreas are being destroyed by their own immune system. If the destruction is not stopped, it can with time lead to type 1 diabetes. Preventive treatment with Diamyd® is intended to intervene in the autoimmune process at an early stage, and thus prevent the disease from developing. Today there is no treatment that can halt the progress of disease in type 1 diabetes.

"It is very exciting to follow the children in this prevention study, which is the first of its kind," says Peter Zerhouni, President and CEO of Diamyd Medical. "This study provides valuable information that can form the basis for larger prevention studies. If it turns out that preventive treatment with our diabetes vaccine reduces the risk of developing type 1 diabetes in these children it would be a great step forward in diabetes research."

The study is being conducted by a research group at Lund University and is led by Dr. Helena Elding Larsson, a pediatrician in Malmö and researcher at Lund University. The study is funded by research grants, but Diamyd Medical has participated in the design of the study and can utilize the study results.

"I think there is a good chance that the diabetes vaccine can have effect in the preventive treatment of children who have not yet been diagnosed with type 1 diabetes," says Helena Elding Larsson. "In DiAPREV-IT, we vaccinate the children early in the disease process when they still have many beta cells left to save and the disease process is not as aggressive as in newly diagnosed, which should increase the chance that the vaccine will have an effect."

DiAPREV-IT, which was started in 2009, is a double-blind, placebo-controlled Phase II study including a total of 50 children aged four and older who through analysis of diabetes markers, so-called auto-antibodies, in the blood are demonstrated to be at high risk of developing type 1 diabetes. Study participants have auto-antibodies against GAD65 and at least one other auto-antibody. Half of the children receive two injections of Diamyd®, and the remaining half receive placebo (inactive substance). The children will be monitored for a total of five years by means of sampling and glucose tolerance tests to evaluate the beta cell function, a measure of the body's own ability to regulate blood sugar. The first results are expected to be compiled three years after the last participant is enrolled, and can thereby be presented in 2015.

Diamyd® has previously been evaluated in a Phase III study of children already diagnosed with type 1 diabetes. The Phase III study did not meet the primary efficacy endpoint of preserving beta cell function. Safety data from the study showed that Diamyd® was well tolerated, as demonstrated by a similar number of adverse events reported across all treatment groups.

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About Diamyd Medical

Diamyd Medical is a Swedish biotech company focusing on the development of pharmaceuticals for the treatment of pain, neuropathy and diabetes. The portfolio of development projects for the treatment of chronic pain and neuropathy uses the Company's patented NTDDS (Nerve Targeting Drug Delivery System) platform to administer therapeutic agents directly to the nervous system. The development project within the area of diabetes consists of the protein GAD65 for the treatment and prevention of autoimmune diabetes.

Diamyd Medical has offices in Sweden and in the US. 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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