



Press release, October 15, 2019

## **Diamyd Medical enters agreement for intralymphatic Diamyd® trial in LADA**

*The agreement with the Norwegian University of Science and Technology in Trondheim (NTNU) refers to a first, investigator initiated clinical Phase II trial with the diabetes vaccine Diamyd® administered directly into the lymph node in a limited number of patients newly diagnosed with LADA (Latent Autoimmune Diabetes in Adults).*

“NTNU has long experience from trials in LADA”, says Ulf Hannelius, CEO of Diamyd Medical. “We are pleased that NTNU wants to use intralymphatic Diamyd® in this interesting patient group. The trial lays the foundation for a valuable broadening of our platform based on Diamyd® intralymphatic immunotherapy.”

“We have identified the diabetes vaccine Diamyd® as one of the most promising therapies for LADA”, says Ingrid K Hals, PhD and Sponsor’s representative for the trial. “There is a great need within LADA for new treatments such as Diamyd® that can be tailored for autoimmune diabetes.”

The application for the planned investigator initiated trial, which is intended to be conducted at clinics in Norway and Sweden, has been submitted to the Norwegian Medicines Agency and decisions are expected during the autumn. The trial is intended to include about 15 patients newly diagnosed with LADA, who are not yet on insulin therapy. The aim of the trial is to evaluate the safety of intralymphatic treatment with Diamyd® in LADA patients and to continuously evaluate the immunological and clinical response over a one-year period. Sponsor of the planned trial is the Norwegian University of Science and Technology with Ingrid K Hals as Sponsor’s representative. Diamyd Medical will contribute with study drug and expertise.

### **About LADA**

Latent Autoimmune Diabetes in Adults (LADA) represents close to 10% of patients diagnosed with type 2 diabetes. LADA is characterized by an ongoing autoimmune destruction of the insulin-producing beta cells, a process similar to that of type 1 diabetes, but slower. Although research categorizes LADA as autoimmune diabetes, the disease is still in most cases treated according to the guidelines for type 2 diabetes. LADA patients are usually not insulin dependent at diagnosis, but for most patients, insulin therapy is required within a few years of diagnosis.

### **About the diabetes vaccine Diamyd® compared to other technologies**

Diamyd® is the world's furthest developed antigen-specific immunotherapy for autoimmune diabetes. Diamyd® is also the only therapy based on the protein GAD65, the antigen that patients diagnosed with type 1 diabetes and LADA most often have antibodies against. Many other immunotherapies are based on peptides, i.e. shorter portions of, for example, insulin proteins, while Diamyd® contains the entire GAD65 as an active component. This means that the whole protein is processed by the body's immune cells in a natural way, without the drug manufacturer having made assumptions about which part of the protein is the most important.

### **About Diamyd Medical**

Diamyd Medical develops the diabetes vaccine Diamyd®, as an antigen-specific immunotherapy for the preservation of endogenous insulin production. Diamyd® has demonstrated good safety in trials encompassing more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company’s own European Phase IIb trial DIAGNODE-2 where the diabetes vaccine is administered directly into a lymph node, two investigator initiated clinical trials are ongoing with Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® for regeneration of endogenous insulin production. An investigator-initiated Remygen® trial in patients living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB and has holdings in the medtech company Companion Medical, Inc., San Diego, USA.

Diamyd Medical’s B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company’s Certified Adviser; phone: +46 8-528 00 399, e-mail: [info@fnca.se](mailto:info@fnca.se).

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