



Press Release, April 9, 2021

## **Fully recruited clinical trial in LADA with Diamyd®**

*The clinical Phase II trial GADinLADA, where the diabetes vaccine Diamyd® is administered directly into the lymph node in patients with the autoimmune form of diabetes LADA (Latent Autoimmune Diabetes in Adults), is fully recruited, and the first results from the trial are planned to be announced in early 2022.*

The first analysis of clinical and immunological parameters will be performed when all patients have been followed for 5 months after their first injection, which means that the results are expected to be presented at the beginning of next year. The patients will be followed for a total of 12 months from the first injection, which means that the final results from the trial are expected to be presented during Q3 2022.

“The fully recruited trial entails a concrete broadening of our platform for intralymphatic immunotherapy with Diamyd® to LADA, where, as in type 1 diabetes, there is a very great need for disease-modifying precision therapies,” says Ulf Hannelius, CEO of Diamyd Medical.

“We have received very positive response from LADA patients to participate in the trial,” says PhD Ingrid K Hals, Sponsor's representative of the trial. “Finding new treatments such as Diamyd®, which can be directly adapted to LADA patients, is very important.”

### **About the GADinLADA trial**

The main aim of the trial is to evaluate the safety of intralymphatic treatment with Diamyd® in patients with LADA (Latent Autoimmune Diabetes in Adults). The patients have been recruited in Norway at the Norwegian University of Science and Technology (NTNU) in Trondheim, in collaboration with St. Olavs Hospital, University Hospital in Trondheim, and in Sweden at the Center for Diabetes, Akademiskt specialistcentrum, an academic specialist unit run in collaboration between Stockholm County's healthcare area, Karolinska Institutet and Karolinska University Hospital. The patients included in the trial are between 30 and 70 years old, have been diagnosed with LADA within the last 18 months and are not yet on insulin therapy. The Sponsor of the trial is the Norwegian University of Science and Technology with Ingrid K Hals as Sponsor's representative. Diamyd Medical contributes with study drugs, expertise and some financial support for immunological analyzes and determination of HLA haplotypes. For more information about the GADinLADA trial, please visit [www.GADinLADA.com](http://www.GADinLADA.com)

### **About LADA**

Latent Autoimmune Diabetes in Adults 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 Diamyd Medical**

Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have been shown in a genetically predefined patient group in a large-scale meta-analysis as well as in the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. A new facility for vaccine manufacturing is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. 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.

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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