



Press Release, August 5, 2022

## Five-month results from Diamyd® trial in LADA published in peer-reviewed scientific journal

*An article presenting the 5-month interim results from the open-label trial GADinLADA that assessed three intralymphatic injections of the therapeutic diabetes vaccine Diamyd®, has been published in the peer-reviewed scientific journal *Frontiers in Endocrinology*.*

As communicated on December 7, 2021, immunological analyses after 5-months showed that the treatment with Diamyd® induced a clear GAD-specific immune response both in term of antibodies and cell-based reactions in individuals diagnosed with LADA.

The publication is entitled "Latent Autoimmune Diabetes in Adults: Background, Safety and Feasibility of an Ongoing Pilot Study With Intra-Lymphatic Injections of GAD-Alum and Oral Vitamin D", and can be accessed at <https://doi.org/10.3389/fendo.2022.926021>

The 12-month top-line results from the trial were communicated on July 7, 2022, showing that the primary endpoints of safety and tolerability were met. Analyses also showed a positive immunological response to the treatment and the clinical course appeared promising with all individuals remaining insulin-independent 12 months after treatment.

The results from the GADinLADA trial will be presented at the EASD diabetes conference to be held in Stockholm on September 19-23, 2022 (<https://www.easd.org/annual-meeting/easd-2022.html>).

### About the GADinLADA trial

The main aim of the trial was to evaluate the safety of three intralymphatic injections of Diamyd® in patients with LADA (Latent Autoimmune Diabetes in Adults). The patients were recruited in Norway at the Norwegian University of Science and Technology (NTNU), Dept. of Clinical and Molecular Medicine, 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 were between 30 and 70 years old, diagnosed with LADA within the last 18 months and were not yet on insulin therapy. The Sponsor of the trial has been the Norwegian University of Science and Technology with Ingrid K Hals, PhD, as Sponsor's representative. Diamyd Medical has contributed with study drugs, expertise and some financial support for immunological analyses and determination of HLA haplotypes.

### 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 precision medicine 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 large 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. DIAGNODE-3, a confirmatory Phase III trial is on-going. A vaccine manufacturing facility 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 individuals 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 as well as in the artificial intelligence company MainlyAI 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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