



Press Release, August 16, 2023

## Results from Diamyd® Antigen-Specific Immunotherapy Trial in LADA published in scientific journal

*Comprehensive 12-month results from the GADinLADA pilot-trial are now published in the peer-reviewed scientific journal Diabetes Obesity and Metabolism. The treatment with Diamyd® of individuals up to 70 years of age diagnosed with LADA, was safe and showed disease modifying potential. The top line results were first announced in July 2022.*

“The published data in this prominent journal brings to light the transformative potential of Diamyd® for LADA patients, aligning closely with the disease-modifying impact seen in type 1 diabetes, says Ulf Hannelius, President & CEO of Diamyd Medical. “We are evaluating the regulatory pathways and possible partnerships to bring this pivotal therapy to LADA patients as we in parallel advance Diamyd® for type 1 diabetes in the first-ever precision medicine phase 3 trial, DIAGNODE-3”.

### Key Highlights:

**Publication Access:** The detailed results evaluating the three intralymphatic injections of Diamyd® in LADA patients are now published in *Diabetes, Obesity and Metabolism*. The article, titled "A one-year pilot study of intralymphatic injections of GAD-alum in LADA individuals with signs of high immunity: no safety concerns and resemblance to juvenile type 1 diabetes", can be accessed at <http://doi.org/10.1111/dom.15239>.

**Safety:** No treatment-related severe adverse events were reported, emphasizing Diamyd®'s safe profile in individuals up to 70 years of age diagnosed with LADA.

**Efficacy and relevance for precision medicine:** Both glucagon-stimulated and mixed-meal stimulated C-peptide measures were employed when evaluating the insulin-producing capacity of the included individuals, showing promising disease modifying treatment efficacy. In line with what has been observed in multiple clinical trials with Diamyd® in Type 1 Diabetes, glucagon-stimulated C-peptide levels indicated preservation of insulin-producing capacity in HLA DR3-DQ2 positive patients ( $P < 0.05$  vs HLA DR3-DQ2 negative patients), further accentuating the specific efficacy of Diamyd® in individuals carrying this genetic marker. All individuals remained insulin-independent at least 12 months post-treatment.

### 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, were not yet on insulin therapy and displayed strong signs of autoimmunity defined as high titers of GAD autoantibodies. 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. Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. DIAGNODE-3, a confirmatory Phase III trial is actively recruiting patients with recent-onset Type 1 Diabetes in eight European countries and is being prepared to start recruiting patients in the US this summer. Significant results have previously 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 Diamyd® was administered directly into a lymph node in children and young adults with recently diagnosed Type 1 Diabetes. A biomanufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the antigen-specific immunotherapy 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. 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.

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