



Press Release, February 29, 2024

Diamyd Medical to present new genetic data at the ASIT summit in Boston, MA

Diamyd Medical is invited as a speaker at the 7th Antigen Specific Immune Tolerance summit to be held in Boston, MA, on March 18-20, 2024. CEO Ulf Hannelius will present up-to-date HLA haplotype frequency data in Type 1 Diabetes collected as part of the ongoing precision medicine Phase 3 trial DIAGNODE-3. The antigen-specific immunotherapy Diamyd® was recently, as previously announced, awarded Fast Track designation by the FDA.

“Genetic data that have been collected from the ongoing Phase 3 trial confirm the previously estimated prevalence of the genetic patient population we are addressing with Diamyd as well as the significance and feasibility of genetic screening for precision medicine immunotherapies”, says Ulf Hannelius, CEO of Diamyd Medical. “The data also provide insights into how the intricate interplay between gender, age and genetics links to the incidence of type 1 diabetes, highlighting the complexity of autoimmune disorders and the importance of personalized therapies like Diamyd”.

The presentation is titled “*Decoding the Future: Leveraging Biomarkers in Antigen-Specific Immunotherapy for Type 1 Diabetes*”, and will focus on the latest insights from genetic HLA typing in the DIAGNODE-3 Phase 3 trial and its potential for the future of diabetes care including screening efforts and personalized treatments.

The antigen-specific immunotherapy Diamyd® was recently, as previously announced, awarded Fast Track designation by the U.S. FDA to improve glycemic control in recently diagnosed stage 3 Type 1 Diabetes patients with the genotype HLA DR3-DQ2.

The HLA data analysis, based on 239 individuals with Type 1 Diabetes screened within the framework of the DIAGNODE-3 trial as of January 9, 2024, confirms that about 50% of all the screened individuals carry the HLA DR3-DQ2 haplotype that has been associated with a positive response to Diamyd® treatment. Also as expected, up to 40% of screened patients fulfill all inclusion criteria for the study. In addition, the data show that 53% of all screened male patients carry the DR3-DQ2 haplotype compared to 45% of all screened female patients. This finding is in line with insights from previous clinical trials with Diamyd® and suggests that in the studied age group of 12- to 29-year-olds, the DR3-DQ2 haplotype is more common in male patients with Type 1 Diabetes compared to female patients.

The Antigen-Specific Immune Tolerance Summit (<https://as-immunetolerance.com/>), taking place on March 18-20 in Boston, MA, gathers leading experts to discuss the latest advancements in antigen-specific immunotherapy. This event is pivotal for professionals dedicated to understanding and enhancing therapies that can specifically target and modulate the immune system in an antigen-specific manner to treat a variety of autoimmune diseases.

About Diamyd Medical

Diamyd Medical develops precision medicine therapies for the prevention and treatment of Type 1 Diabetes and LADA (Latent Autoimmune Diabetes in Adults). Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production that has Orphan Drug Designation in the U.S. and in February 2024 was granted Fast Track designation by the U.S. FDA. DIAGNODE-3, a confirmatory Phase III trial is actively recruiting patients with recent-onset Type 1 Diabetes in eight European countries and in the U.S. Significant clinical benefits on preservation of C-peptide and improved glycemic control have previously been shown in the sizable patient group carrying the genetic HLA DR3-DQ2 marker identified using routinely available blood tests. These statistically significant effects were seen in a large-scale meta-analysis as well as in the Company’s European Phase IIb trial, where Diamyd® was administered directly into a superficial lymph node in children and young adults with recently diagnosed Type 1 Diabetes. Injection into a superficial lymphnode is a well-tolerated procedure performed within minutes and is intended to optimize the immune response. A biomanufacturing facility for the manufacture of recombinant GAD65 protein, the active ingredient in the antigen-specific immunotherapy Diamyd®, is under development in Umeå, Sweden. Diamyd Medical also develops the GABA-based

investigational drug Remygen® as a component in the treatments of metabolic diseases. Diamyd Medical is a major shareholder 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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