



Press Release, November 7, 2023

Diamyd Medical partners with DiaUnion to recruit participants for Type 1 diabetes prevention trial

Diamyd Medical has entered into a collaboration agreement with DiaUnion, a center of excellence in type 1 diabetes, to identify participants for the DiaPrecise trial, an open-label trial evaluating the safety, feasibility and immune response of intralymphatic injections of Diamyd® in children at risk of developing type 1 diabetes who also carry the HLA DR3-DQ2 genotype. The DiaPrecise trial has been initiated and is ongoing at the Department of Clinical Sciences at Lund University, Malmö, with Markus Lundgren M.D., PhD, as the Principal Investigator.

“We are thrilled to partner with DiaUnion around the precision medicine trial DiaPrecise”, says Ulf Hannelius, President & CEO of Diamyd Medical. “An infrastructure for screening of type 1 diabetes is a prerequisite to evaluate preventive treatments, and this partnership is important to advance our goal of delaying or preventing the progression of type 1 diabetes with the antigen-specific immunotherapy Diamyd”.

DiaPrecise is the first precision prevention trial with Diamyd®, and is conducted under the ASSET program (AI for the Sustainable Prevention of Autoimmunity in Society, www.asset.healthcare) funded by the Swedish Innovation Agency VINNOVA. DiaUnion is a consortium coordinated by the Medicon Valley Alliance involving also the Steno Diabetes Center Copenhagen and Lund University, Malmö, establishing a screening program to identify individuals positive for diabetes autoantibodies, and there at high risk for the disease.

“DiaUnion's long term goal is to prevent type 1 diabetes”, says Finn Kristensen, Program Director, DiaUnion. “Screening programs currently constitute a bottleneck for the identification of persons at risk and thus for the development of new therapies. We are excited to enter into our first industry partnership with Diamyd Medical as a step towards this goal”.

About DiaPrecise – Precision Prevention of Type 1 Diabetes

DiaPrecise is an open-label clinical trial where Diamyd® (GAD-alum) is given directly into a lymph node in 10 to 16 children aged 8 to 18 years who are at high risk of being diagnosed with clinical Type 1 Diabetes (so called Stage 1 or Stage 2 Type 1 Diabetes), and who also carry the genetically defined haplotype HLA DR3-DQ2, associated with clinical response to Diamyd®. The aim of the trial is to evaluate the safety and feasibility of two or three intralymphatic injections with Diamyd® as well as the effect on the immune system and clinical parameters including endogenous insulin production and blood glucose control. The Principal Investigator of DiaPrecise is Dr. Markus Lundgren, Researcher at the Department of Clinical Sciences at Lund University and consultant pediatrician at Kristianstad hospital, Sweden. Sponsor of the trial is Diamyd Medical.

About DiaUnion

DiaUnion is a consortium coordinated by the Medicon Valley Alliance involving a research collaboration between, the Steno Diabetes Center Copenhagen and Lund University, Malmö. DiaUnion is now establishing a screening program based on ground-breaking new multiplex analysis methods that significantly streamlines laboratory work. So far, around 4,500 people from Denmark and Sweden have been screened, and the plan is subsequently increase the number of screenings over the next 3-5 years. The screening program forms the basis for the prevention of type 1 diabetes, celiac disease and autoimmune thyroiditis through new therapies to delay and stop the development of the disease, and at the same time strengthens the continued clinical development of therapies against these and other autoimmune diseases. The program is funded by the EU Interreg ÖKS with Region H, Region Skåne, Steno Diabetes Center, Lund University and Novo Nordisk as partners.

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 in the US. 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 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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The information was provided by the contact person above, for publication on November 7, 2023, 12.00 CET.