Press Release, May 19, 2022

First patient enrolled in Diamyd Medical's Phase III trial DIAGNODE-3

The first patient has now received its first intralymphatic injection of Diamyd® in the precision medicine Phase III trial DIAGNODE-3. The trial will include approximately 330 patients aged 12 to 29 years newly diagnosed with Type 1 Diabetes who carry the genetically defined haplotype HLA DR3-DQ2.

"The fact that the first patient is now enrolled in DIAGNODE-3 is a major milestone for the therapeutic diabetes vaccine Diamyd," says Ulf Hannelius, CEO of Diamyd Medical. "The Phase III trial is based on decisive scientific achievements in precision medicine, robust data, a unique and safe treatment and solid preparatory work that increases the likelihood of success."

"Preserving some own insulin secretion is the best way to mitigate type 1 diabetes, prevent complications and provide a good quality of life," says Johnny Ludvigsson, Professor at Linköping University and Coordinating Iinvestigator for DIAGNODE-3. "To be able to achieve this with a simple treatment free of risks would be a breakthrough".

More patients will be included shortly. A total of 18 clinics have now been opened, which includes at least one clinic in each approved country (Sweden, the Netherlands, Spain, Poland, Germany and the Czech Republic). More clinics in these countries will be opened in the coming weeks and work to gradually expand the number of participating European countries and clinics is ongoing.

More clinical updates:

The last patient visit has been conducted in the open-label investigator-initiated clinical trial GADinLADA, where the diabetes vaccine Diamyd® is administered directly into the lymph node in 14 patients aged 30 – 70 years with the autoimmune form of diabetes called LADA (Latent Autoimmune Diabetes in Adults). The results are expected to be presented in the third quarter of this year.

The investigator-initiated clinical trial DIAGNODE-B, (B as in Booster), has in a short time included 4 patients, which is the majority of the intended patients from the previous trials DIAGNODE-1 and DIAGNODE-2. The trial will evaluate the safety, the impact on the immune system and the clinical efficacy of an additional injection with the antigen-specific immunotherapy Diamyd®. The patients will receive the booster injections within the next month.

About DIAGNODE-3
The Phase III trial DIAGNODE-3, with the therapeutic vaccin Diamyd®, willl enroll approximately 330 individuals aged 12 to 28, recently diagnosed with type 1 diabetes, who carry the HLA DR3-DQ2 haplotype. This patient population is based on clinical efficacy and safety results from the Phase IIa and Phase IIb trials DIAGNODE-1 and DIAGNODE-2, as well as on the large-scale meta-analysis encompassing data from more than 600 individuals from previous Phase II and Phase III trials using Diamyd®. A further stratification for HLA haplotypes will be included in order to evaluate the potential super responder group of individuals who are positive for HLA DR3-DQ2 and negative for HLA DR4-DQ8.

The Phase III trial will be conducted at approximately 50 clinical sites. Following a run-in period where all subjects receive vitamin D for one month, subjects will be randomized 2:1 to receive three intralymphatic injections of Diamyd® or matching placebo given one month apart, with a primary efficacy readout at 24 months from baseline. The design provides, based on efficacy data from previous trials on the HLA restricted patient population, a high probability to reach its primary endpoints: 1) preservation of endogenous insulin producing capacity measured as stimulated C-peptide, and 2) improved blood glucose control measured as HbA1c. Sponsor of the trial is Diamyd Medical.

About GADinLADA
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

About DIAGNODE-B
DIAGNODE-B is an open-label investigator-initiated clinical trial planned to enroll Type 1 Diabetes patients who carry the genetically defined haplotype HLA DR3-DQ2 and are previously treated with intralymphatic injections of Diamyd® at Crown Princess Victoria Children's Hospital in Linköping. The trial is planned to include approximately 6 patiens who have either been treated with four injections in DIAGNODE-1, who will then receive a 5th intralymphatic injection of Diamyd®, or patients who participated in DIAGNODE-2, who will receive a 4th intralymphatic injection of Diamyd®, approxinmately 4 years after the last injection. The aim of the trial is to evaluate the safety of a booster (fourth/fifth) injection with Diamyd® and the effect on the immun system and the endogenous insulin production. The patients will be followed for 12 months after injection.The trial will be conducted at the Clincal Resarch Unit at the University Hospital in Linköping. Sponsor of the trial is Linköping University with Professor Johnny Ludvigsson as Sponsor's representative. Diamyd Medical contributes with study drug, expertise and some financial support.

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

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