Press Release, September 5, 2023

Registrational Phase III trial in Type 1 Diabetes with Diamyd® expands to the US

The first clinical site in the United States is pending imminent initiation in the precision medicine Phase III trial DIAGNODE-3, which is ongoing in eight European countries. DIAGNODE-3 is designed to confirm the efficacy and safety of the antigen-specific immunotherapy Diamyd® in patients aged 12 to 29 years recently diagnosed with type 1 diabetes and carrying the genetic HLA DR3-DQ2 marker. The goal is to have the trial fully enrolled in the second half of 2024.

Final preparations are in place to initiate the first clinical site for DIAGNODE-3 in the United States, and additional sites are expected to be initiated over the coming months. Approximately 10-12 clinical sites across the US are planned to be initiated, expanding the DIAGNODE-3 trial in the US and eight European countries to approximately 60 clincal sites in total. An Investigators' Meeting for the US clinical sites will be held on September 15th in Washington DC with several US key opinion leaders in attendance.

Approximately 40% of all screened patients carry the genetic HLA DR3-DQ2 haplotype. This proportion aligns well with expectations based on previous Diamyd® clinical trials and published epidemiological research. Supported by published retrospective analyses and prospective clinical trials, the presence of the genetic HLA DR3-DQ2 haplotype determines the likelihood of responding to Diamyd® therapy, and serves as one of the main inclusion criteria in the DIAGNODE-3 trial.

"Patient recruitment is a complex and central element in any trial and it is encouraging to see a significant and continuous uptick in the screening rate and that the observed frequency of the genetically defined responder group enrolled into DIAGNODE-3 confirms our previous observations", says Ulf Hannelius, President & CEO of Diamyd Medical. "This shows the operational and clinical feasibility of our precision medicine approach to Type 1 Diabetes and we look forward to expanding the trial to the United States".

The screening rate (the average number of patients assessed for eligibility per site during a period of time) in DIAGNODE-3 has steadily been increasing in recent months and is in line with comparable late-phase clinical trials in Type 1 Diabetes. The trial has reached and passed operational recruitment milestones defined in the Industry Discovery & Development Partnership with JDRF that was announced in April 2023 (read the press release here). Additional milestones will be reached as the trial expands to the US. The partnership with JDRF, the largest Type 1 Diabetes patient advocacy organisation in the US, forms the backbone of Diamyd Medical's focus on completing enrolment of the registrational trial within the expected timeframe.

About DIAGNODE-3

The confirmatory Phase III trial DIAGNODE-3 (www.diagnode-3.com), evaluating the safety and efficacy of the antigen-specific immunotherapy Diamyd® in individuals diagnosed with Type 1 Diabetes is ongoing in eight European countries: Sweden, Spain, the Czech Republic, the Netherlands, Germany, Poland, Hungary and Estonia. Approximately 50 clinics are activated in Europe and approximately 10-12 sites will be activated in the United States.

DIAGNODE-3 will enroll approximately 330 individuals aged 12 to 29 years, recently diagnosed with type 1 diabetes, who carry the HLA DR3-DQ2 haplotype. A further stratification for HLA haplotypes is 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.

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®. The trial design provides a high probability to reach its co-primary endpoints of preservation of endogenous insulin producing capacity measured as stimulated C-peptide and improved blood glucose control as determined by HbA1c.

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 recruting patients with recent-onset Type 1 Diabetes in eight European countries and will soon start recruiting patients 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 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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