Press Release, November 26, 2022

US Partial Clinical Hold on Diamyd® Phase III Trial Lifted by the FDA

Diamyd Medical announced today that the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold on the confirmatory Phase III trial DIAGNODE-3, evaluating the safety and efficacy of the precision medicine and antigen-specific immunotherapy Diamyd® in individuals recently diagnosed with type 1 diabetes. Following the decision from the FDA, DIAGNODE-3 is approved to start in the US.

"This is a significant milestone for Diamyd Medical and more importantly, for patients diagnosed with type 1 diabetes," comments Ulf Hannelius, CEO of Diamyd Medical. "We are looking forward to moving ahead with DIAGNODE-3 in the US and we will work diligently with investigators and patient groups to make sure that our therapy can be made available to type 1 diabetes patients in need."

The FDA issued a partial clinical hold on the pivotal DIAGNODE-3 trial in September 2021, pausing the start of the trial in the US. Several interactions have been held with the FDA since then to resolve questions raised by the agency. Diamyd Medical will immediately resume the process of interacting with clinical sites and institutional review boards with the aim of including US clinical sites in the trial. DIAGNODE-3 is approved and actively recruiting patients in eight European countries.

About DIAGNODE-3
The Phase III trial DIAGNODE-3, with the antigen-specific immunotherapy Diamyd®, will 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 more than 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 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. 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 manufacturing 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. 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.

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This information is information that Diamyd Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was provided by the contact person above, for publication on November 26, 2022, 13.20 CET.