Press Release, October 18, 2021

Diamyd Medical to initiate its Type 1 diabetes Phase III trial in Europe as discussions continue with FDA regarding partial clinical hold in the US

The U.S. Food and Drug Administration (FDA) has requested additional data to support Diamyd Medical's IND application for DIAGNODE-3, a Phase III trial with the diabetes vaccine Diamyd® in recent onset type 1 diabetes. Outstanding questions largely pertain to manufacturing of the study drug and need to be addressed before FDA's partial clinical hold for the Phase III trial in the US can be lifted. Given the delay this may entail, Diamyd Medical will commence its initiation of the Phase III trial in Europe, while interactions with the FDA continue.

To lift the partial clinical hold on DIAGNODE-3, first announced on September 17, 2021, the FDA has requested additional data to provide clarity pertaining to the manufacturing of the study drug to be evaluated in DIAGNODE-3 including the manufacturing process being established at Diamyd Medical's manufacturing facility in Umeå.

Given the estimated time required to answer the outstanding questions from the FDA, Diamyd Medical will focus the initiation of DIAGNODE-3 in Europe with a plan to extend the number of participating European countries and clinics in order to maintain recruitment timelines. Diamyd Medical will in parallel work with the FDA to resolve any additional outstanding questions, in order to lift the partial clinical hold.

The start of DIAGNODE-3 is approved by the Swedish MPA, and additional European countries are pending.

"In light of the great interest shown in the precision medicine approach with the diabetes vaccine Diamyd®, it is of course unfortunate if we, due to the continued partial clinical hold, will miss out on including individuals from the United States in the DIAGNODE-3 trial", says Ulf Hannelius, CEO of Diamyd Medical. "We will work closely with the FDA to resolve the outstanding questions while increasing participating countries and sites in Europe to maintain the operational timelines for DIAGNODE-3."

CEO Ulf Hannelius will comment on this press release in a live video interview arranged by Nyhetsbyrån Direkt at 1:00 pm. CET today; https://youtu.be/OLGTd4guOc8

About DIAGNODE-3
The Phase III trial DIAGNODE-3, with a planned start date later during 2021, is designed to 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.

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. Preparations for a confirmatory Phase III trial are on-going, to start recruting patients later in 2021. 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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