Press Release, September 17, 2021

FDA pauses start of DIAGNODE-3 in the US pending clarification on study drug

The start of the Phase III trial DIAGNODE-3 in the United States is being paused by the US Food and Drug Administration (FDA) to clarify certain outstanding questions regarding the study drug. Diamyd Medical will be notified of which questions that are outstanding within 30 days.

A so-called "partial clinical hold" means that the FDA has not yet approved all parts of a study submission. The FDA has informed that it does not yet have sufficient information on questions concerning the study drug. The FDA will within 30 days provide more details on what information needs to be supplemented in order to start the trial in the United States.

"We will of course treat the FDA's qustions with the highest priority in order to start the trial as soon as possible in the US", says Ulf Hannelius, CEO of Diamyd Medical. "Pending further information from the FDA, work is continuing at full pace regarding applications and approvals for DIAGNODE-3 in other countries."

About DIAGNODE-3
The Phase III trial DIAGNODE-3, with a planned start date later during 2021 and primary completion end of 2025, 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 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 in Europe and the United States. 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 co-primary endpoint regarding preservation of endogenous insulin producing capacity measured as stimulated C-peptide and 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 in the US and Europe 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 patients 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.

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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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 September 17, 2021, 12.20 CET.