Press Release, September 21, 2021

Diamyd Medical receives first regulatory approval to start the Phase III trial DIAGNODE-3 with the diabetes vaccine Diamyd®

Diamyd Medical announces today that The Swedish Medical Products Agency has given approval for the start of DIAGNODE-3, a placebo-controlled precision medicine Phase III trial with the diabetes vaccine Diamyd®. The trial is designed to confirm the efficacy and safety of Diamyd® in individuals recently diagnosed with type 1 diabetes, who carry the genetically defined haplotype HLA DR3-DQ2.

"This is very gratifying and an important milestone for DIAGNODE-3," says Ulf Hannelius, CEO of Diamyd Medical. "We continue working at full pace with the applications and approvals in the other countries".

A statement from the Swedish Ethical Review Authority is awaited in order to recruit patients in Sweden. The plan is to start the first clinic in Sweden before year-end.

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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