Press Release, April 29, 2021

The 24-month follow-up of DIAGNODE-2 with the diabetes vaccine Diamyd® will be presented in early July

All 50 patients who participated in the extension of Diamyd Medical's Phase IIb trial DIAGNODE-2 with the diabetes vaccine Diamyd® have now made their 24-month visit, and data will be presented in early July, but without formal statistical evaluation, as the data refers to a selection of the total of 109 patients in the trial. The top-line results from 15 months were presented in September 2020. The work of starting the Phase III trial DIAGNODE-3 is in full speed with identification and contact with clinics in the USA and Europe.

The primary end-point for the DIAGNODE-2 trial was read after 15 months and the top-line results were presented in September 2020. In order to strengthen the database on intralymphatic administration, from the autumn of 2019, the 55 patients who had not yet completed their last visit at 15 months were offered to participate in an extension of the trial for another 9 months, thus a total of 24 months. 50 patients participated in the extension and have now made the extra visit at 24 months. Of these, approximately half are estimated to carry the genetically defined haplotype HLA DR3-DQ2 which is linked to the clinical effect of the diabetes vaccine Diamyd®. The collected data will undergo extensive quality control at the clinics and in the electronic database. The database will then be locked and data will be presented in early July. As only a selection of the 109 patients in the trial were followed for 24 months, the results will be presented descriptively without any formal statistical evaluations.

The work to start Diamyd Medical's Phase III trial, DIAGNODE-3, is ongoing in collaboration with ICON, the chosen CRO. An important initial activity is the selection of clinics in the USA and Europe, where patient recruitment capacity is an important selection criterion. The trial will include approximately 330 individuals aged 12 to 28 who have been recently diagnosed with type 1 diabetes and who carry the genetically defined haplotype HLA DR3-DQ2. The trial is expected to begin recruiting patients later this year.

As previously announced, the clinical Phase II trial GADinLADA, in which the diabetes vaccine Diamyd® is administered directly into the lymph node in patients with the autoimmune form of diabetes LADA (Latent Autoimmune Diabetes in Adult), is now fully recruited. The first analysis of clinical and immunological parameters will be performed when all patients have been followed for 5 months after the first injection, which means that the results are expected to be presented at the beginning of next year. Preparations for this have begun.

About DIAGNODE-2
The placebo-controlled trial DIAGNODE-2 encompasses 109 patients from Spain, the Czech Republic, Sweden and the Netherlands, aged 12−24 years. The patients, recently diagnosed with type 1 diabetes, have been given the diabetes vaccine Diamyd® (or its placebo) directly into the lymph node on three occasions, one month apart, in combination with oral vitamin D (or its placebo) during four months, starting 30 days prior to the first injection. The patients have been followed for 15 months with the aim to evaluate the remaining insulin producing capacity. As of the autumn of 2019, patients who had not yet completed their last visit at 15 months were offered to participate in an extension of the study for another 9 months. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University. Sponsor for the trial is Diamyd Medical. For more information about the trial, see www.diagnode-2.com.

About DIAGNODE-3
The placebo-controlled Phase III trial DIAGNODE-3 will include approximately 330 individuals aged 12 to 28 who have been recently diagnosed with type 1 diabetes and who carry the genetically defined haplotype HLA DR3-DQ2. The trial will be conducted at approximately 50 clinics in Europe and the United States, where almost half of all individuals with type 1 diabetes are estimated to carry the current haplotype. After an initial month in which all trial participants receive vitamin D, the individuals will be randomized 2:1, ie two out of three trial participants will receive three intralymphatic injections of Diamyd® and one in three will receive the corresponding placebo at one month intervals, with one primary reading 24 months after trial start. The design provides, based

on efficacy data from previous studies on the HLA-restricted patient population, a high probability of reaching the primary end-points; preservation of stimulated C-peptide and lower HbA1c. The Coordinating Investigator for the trial is Professor Johnny Ludvigsson at Linköping University. The Sponsor of the trial is Diamyd Medical.

About Diamyd Medical
Diamyd Medical develops 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 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. A new facility for vaccine manufacturing 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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